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2	2180	sensor same cable same connector	USPAT	2003/09/29 09:36
3	78	600/325.ccls. or 600/327.ccls. or 600/332.ccls. or 600/339.ccls.	USPAT	2003/09/29 09:47
4	203	600/505.ccls.	USPAT	2003/09/29 10:04
5	221	600/345-365.ccls. and catheter	USPAT	2003/09/29 10:39
6	326	(sensor same cable same connector) and 600/$.ccls.	USPAT	2003/09/29 10:22
7	320	((sensor same cable same connector) and 600/$.ccls.) not (600/345-365.ccls. and catheter)	USPAT	2003/09/29 10:22
8	315	(((sensor same cable same connector) and 600/$.ccls.) not (600/345-365.ccls. and catheter)) not (600/325.ccls. or 600/327.ccls. or 600/332.ccls. or 600/339.ccls.)	USPAT	2003/09/29 10:38
9	61	600/345-365.ccls. and bead$	USPAT	2003/09/29 10:40
10	27	sensor same (bead$ with encapsulat$)	USPAT	2003/09/29 11:42
11	1209	bead$ with encapsulat$	USPAT	2003/09/29 10:46
12	12	(bead$ with encapsulat$) and 73/$.ccls.	USPAT	2003/09/29 10:43
13	1	(bead$ with encapsulat$) with detector$	USPAT	2003/09/29 10:46
14	2	(bead$ with encapsulat$) same detector$	USPAT	2003/09/29 11:42
15	47	600/$.ccls. and (sensor with bead$)	USPAT	2003/09/29 11:50
16	221	600/345.ccls.	USPAT	2003/09/29 11:57
17	17	600/322-324.ccls. and bead$	USPAT	2003/09/29 12:14
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26	48	600/374.ccls.	US-PGPUB	2003/09/29 13:37
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30	7	(ribbon adj cable) and 600/374.ccls.	USPAT; US-PGPUB	2003/09/29 13:38

United States Patent [19]

Rich et al.

[11] **Patent Number: 4,865,038**

[45] **Date of Patent: Sep. 12, 1989**

[54] **SENSOR APPLIANCE FOR NON-INVASIVE MONITORING**

[75] Inventors: **David Rich**, E. Hartford, Conn.; **Simon Thomas**, Whitland, Wales

[73] Assignee: **Novametrix Medical Systems, Inc.**, Wallingford, Conn.

[21] Appl. No.: **916,938**

[22] Filed: **Oct. 9, 1986**

[51] **Int. Cl.**[4] **A61B 5/00**

[52] **U.S. Cl.** **128/633**; 128/664; 128/665; 356/41

[58] **Field of Search** 128/644, 666, 696, 633, 128/639, 664, 665, 690, 798, 802; 356/41; 250/551

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,091,803	5/1978	Pinder	128/690
4,129,124	12/1978	Thalmann	128/690
4,160,308	7/1979	Courtney et al.	250/551
4,213,463	7/1980	Osenkarski	128/639
4,233,987	11/1980	Feingold	128/639
4,380,240	4/1983	Jobsis et al.	128/633
4,635,641	1/1987	Hoffman	128/639
4,636,647	1/1987	Nishizawa	250/551
4,700,708	10/1987	New, Jr. et al.	128/633
4,726,382	2/1988	Boehmer et al.	128/667

Primary Examiner—Ruth S. Smith

Attorney, Agent, or Firm—Howard F. Mandelbaum

[57] **ABSTRACT**

A sensor appliance removably attachable to a living body for non-invasively producing signals indicative of a condition of the body and applying them to a monitoring or measuring device and method of making the appliance characterized by a small, highly flexible light weight substrate with surface mounted light emitting and photodetector components hermetically sealed in a flexible moisture resistant envelope. Provision is made for inclusion of a form sustaining spine to enhance positional stability.

17 Claims, 2 Drawing Sheets

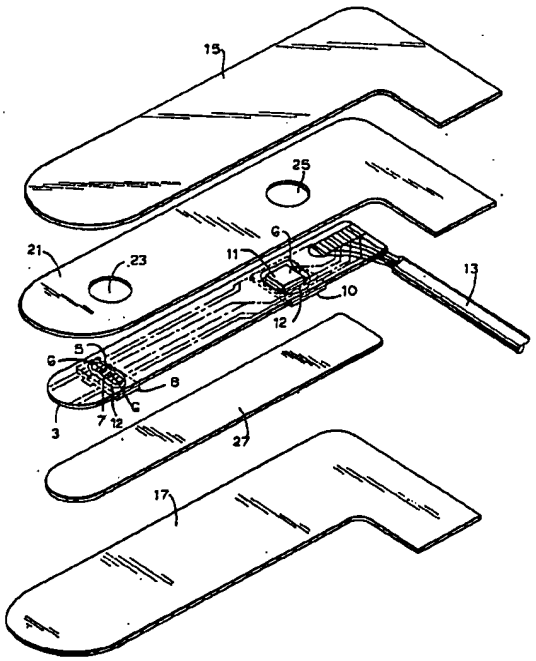


FIG. 1

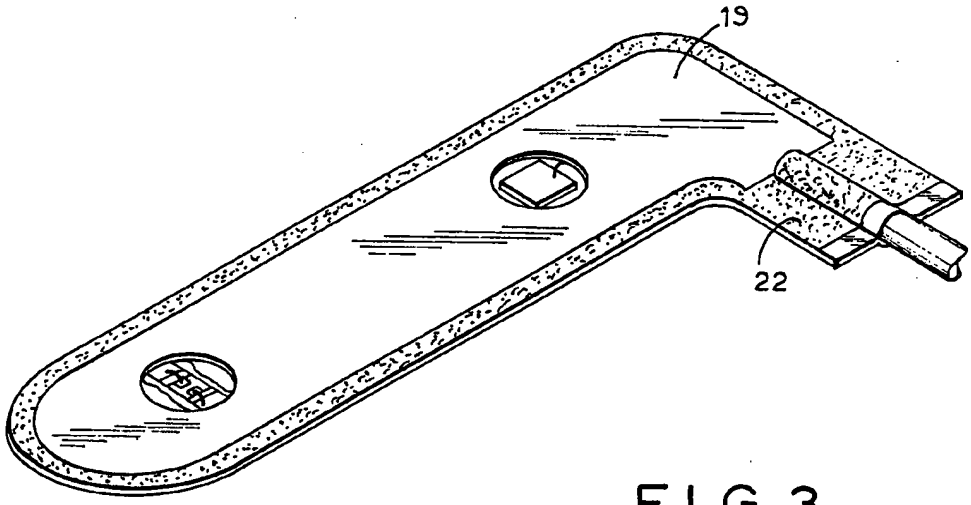


FIG. 3

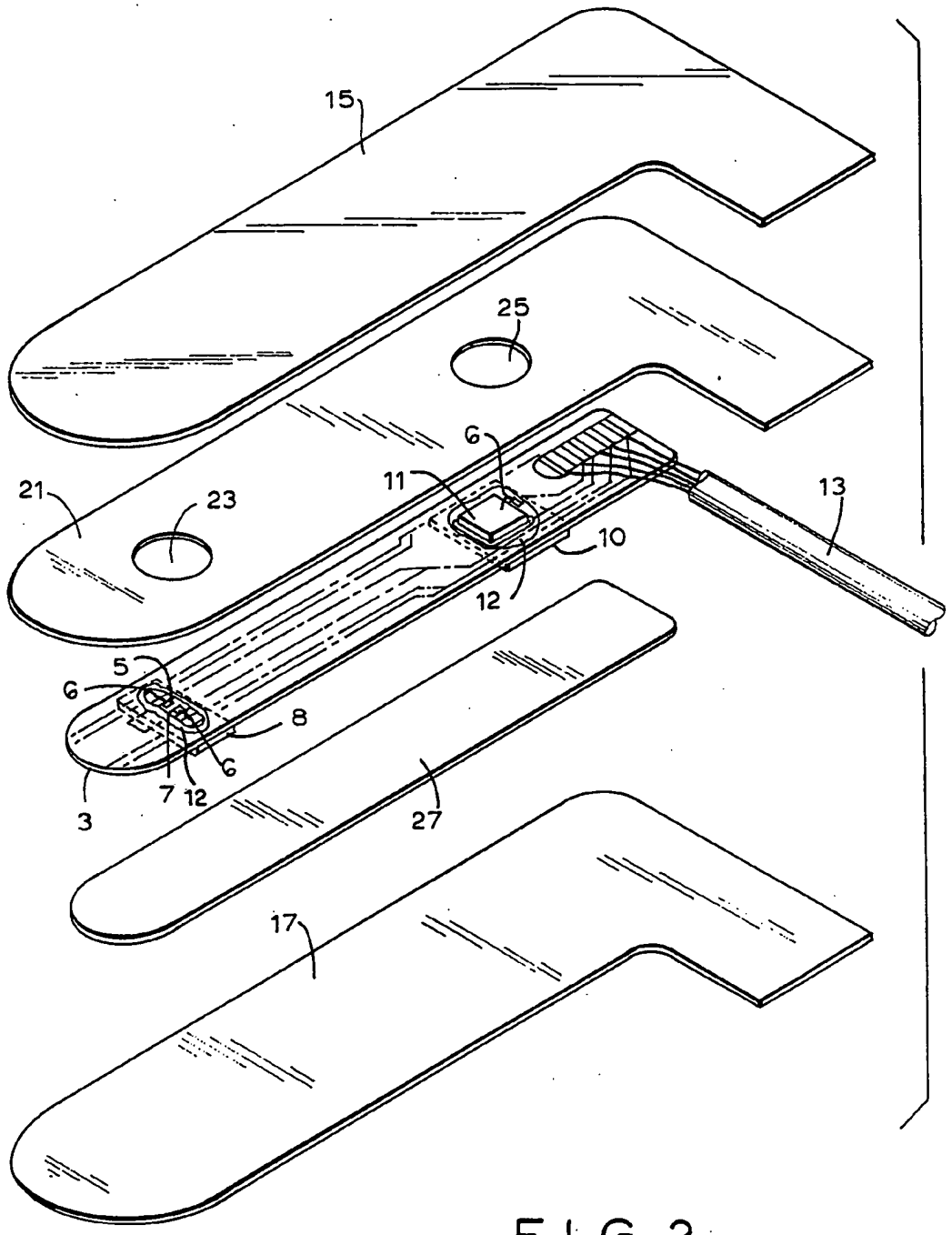


FIG. 2

SENSOR APPLIANCE FOR NON-INVASIVE MONITORING

BACKGROUND OF THE INVENTION

This invention is related to the use of sensors applied to the body for monitoring or making measurements of body tissue condition, metabolism or other body functions indicative of health. More specifically, the invention is directed to an appliance which can be readily attached to the body to support a sensor adjacent thereto in a stable disposition for accurate and precise measurements unhampered by artifact due to sensor motion relative to the body.

One application for a sensor appliance of the type described herein is in pulse oximetry, a non-invasive method of measuring the relative oxygen saturation of the blood. Pulse oximeters generally employ light sources, e.g., light emitting diodes (L.E.D.s), to alternately direct light of two different wave lengths, e.g., red and infra-red, to the blood through the skin. The light transmitted or reflected by the blood at the different wave lengths can then be compared to provide a measurement of oxygen saturation.

Typically, a sensor appliance containing the light sources, e.g., L.E.D.s, and a light sensor, e.g., photodetector, is mounted on the finger, toe or ear lobe. An example of such a sensor is disclosed in European patent application No. 84302994.3 for a Sensor having Cutaneous Conformance. In prior art sensor appliances, individual L.E.D.s and a photodetector of an oximeter sensor are each mounted on a respective rigid substrate which is, in turn, incorporated into a flexible envelope, making for a bulky device which often result in unstable readings due to limited conformability when attached to a patient. In addition to yielding unstable readings due to limited conformability, prior art appliances are subject to contamination and suitable for use only as disposable devices since their discrete LED and photodiode components and wiring are relatively bulky and vulnerable to external contaminants. Moreover, such appliances cannot be readily cleaned for use on multiple patients. Flexibility in the areas of the light sources and detectors is minimal thereby preventing good conformance with small toes, fingers and earlobes as in the case of neonates. In addition, disassembly of and/or damage to the structure of prior art appliances often results from attempts at repeated usage.

SUMMARY OF THE INVENTION

The foregoing problems and others associated with prior art sensor appliances are overcome by the instant invention which provides for a sensor appliance adapted for removable attachment to a living body for non-invasively producing signals indicative of a condition of the body and applying them to a monitoring or measuring device, including an elongated flexible substrate disposed within an outer flexible sealed envelope and having energy transmitting means and sensor means integrally bonded therewith and signal conductor means operatively connected to said sensor means for connection to a monitoring or measuring device, and rigid support means bonded to an opposite side of said substrate adjacent the sensor means for enhancing wire bonding and preventing delamination of the encapsulating epoxy of the appliance structure during flexing thereof.

It is therefore an object of the invention to provide a sensor appliance adapted for removable attachment to a living body for non-invasively producing signals indicative of a condition of the body.

Another object of the invention to provide a sensor appliance suitable for repeated use among several patients.

Still another object of the invention to provide a sensor appliance which is conformable to the surface of the body at which it is positioned thereby resisting motion with respect to the body.

A further object of the invention to provide a sensor appliance which can be readily disinfected between uses.

Still a further object of the invention to provide a sensor appliance having a very low profile for enhanced flexibility.

An additional object of the invention to provide a sensor appliance which is hermetically sealed so that its active components are impervious to contamination.

Other and further objects of the invention will be apparent from the following drawings and description of a preferred embodiment of the invention in which like reference numerals are used to indicate like parts in the various views.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is an environmental view of the preferred embodiment of the invention in its intended use.

FIG. 2 is an exploded perspective view of the preferred embodiment of the invention.

FIG. 3 is a perspective view of the preferred embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIG. 1 of the drawings, there is shown a sensor appliance 1, in accordance with the invention, disposed on the finger of a patient. The sensor appliance 1, as shown, is used in oximetry, i.e., the measurement of percent oxygen saturation of the blood. However, it is to be appreciated that the structure disclosed herein may have application in other measurements or monitoring of body condition, function or metabolism where it is desired to mount a sensor on the body of a patient.

Referring now to FIGS. 2 and 3 of the drawings, there is shown an elongated flexible printed circuit board substrate 3 having a very low profile, i.e., a thickness of approximately 0.15 millimeters. The flexible substrate 3 is preferably formed from a strong, light weight material suitable for component surface mounting and wire bonding.

Two die light emitting diodes 5 and 7 are respectively bonded to the flexible printed circuit board substrate 3 by a suitable bonding agent which, in the case of the preferred embodiment of the invention is a die attachment epoxy that forms a first bond to the flexible printed circuit board substrate 3. The die attachment epoxy is selected to have high thermal conductivity thereby serving as a heat sink and dissipating the heat generated by the LEDs 5 and 7 when they are energized. The die attachment epoxy is also selected to have high electrical conductivity. A second contact to the L.E.D. dice is made by means of wire bonds 6 between the die contact pads and appropriate adjacent tracks formed by conductors 9 on the printed circuit board.

As is known in oximetry, the transmission of light in the red range of the spectrum, i.e., at a wave length of approximately 660 nanometers through blood is substantially affected by the amount of oxygenated hemoglobin present in the blood. The transmission of light in the infra-red range of the spectrum, i.e., at a wave length of approximately 940 nanometers through blood is substantially unaffected by the amount of oxygenated hemoglobin present in the blood. Oximeters use this principal to alternately illuminate the blood through the skin tissue with light of the foregoing respective wave lengths. Hence, in accordance with the present invention, the LED **5** emits light in the red range at 660 nm and the LED **7** emits light in the infra-red range at approximately 940 nm. The die LEDs **5** and **7** include no separate wire leads or package as found in conventional LEDs but only the light emitting elements which are die attached and wire bonded directly to suitably plated copper conductors **9** on the surface of the flexible printed circuit board substrate **3** through which the die LEDs **5** and **7** are alternately energized. In the preferred embodiment of the invention, the copper conductors **9** are plated with 0.99999 pure neutral gold. Other materials having similar conductivity may be employed. The substrate **3** can be in the form of a flexible circuit such as a commercially available Kapton flex circuit.

Also mounted on the flexible printed circuit board substrate **3** at its opposite end is a die photodetector **11** which is directly die attached and wire bonded to other copper conductors **9** for transmitting signals produced by the die photodetector **11** to an oximeter or other monitor (not shown) through a cable **13**. Like the die LEDs **5** and **7**, the die photodetector **11** includes no separate wire leads or package as found in conventional photodetectors but only the light detecting element, the two contacts of which are die attachment epoxy and wire bonded, respectively, directly to suitably plated copper conductors **9** on the surface of the flexible printed circuit board substrate **3** through which the output signals produced by the die photodetector **11** are transmitted to the oximeter or monitor.

The die LED **5** and **7**, and the die photodetector **11** are covered with an encapsulating mound **12** formed from a glob-top epoxy, that is, a high viscosity epoxy which does not flow beyond the area to which it is applied and hardens into a bead having a substantially smooth and spherical exposed surface, which is transparent to light having a wave length in the range of 660 nanometers to 940 nanometers. The glob-top epoxy mound **12** forms a rigid protective shield which helps stabilize the die LED **5** and **7**, and die photodetector **11** relative to the flexible printed circuit board substrate **3** and which absorbs any external impact which may be applied to the die LED **5** and **7** and die photodetector **11**.

Bonded to the underside of the substrate **3**, immediately beneath the LEDs **5** and **7**, and die photodetector **11** are rigid supports **8** and **10**. The supports **8** and **10** are preferably made of a light weight rigid material, e.g., a rigid plastic or reinforced epoxy to provide local support only in the areas of the LEDs **5** and **7**, an die photodetector **11** to facilitate die attachment and wire bonding without significantly compromising the flexibility of the substrate **3** and appliance **1** as a whole.

The flexible printed circuit board substrate **3** with the die LEDs **5** and **7**, die photodetector **11**, and suitably plated copper conductors **9** mounted on it is sandwiched between the upper and lower layers **15** and **17**, respectively of a vinyl envelope **19**. The lower layer **17** is preferably formed from a sheet of highly flexible white opaque vinyl or similar material. The upper layer **15** is preferably formed from a sheet of highly flexible transparent vinyl or similar material to enable light to be transmitted from the die LEDs **5**, **7**, through the upper envelope layer **15**, and after passing through the body tissue, again through the upper envelope layer **15**, to the die photodetector **11**.

Disposed between the upper envelope layer **15** and lower envelope layer **17** is a spacer **21** formed from a sheet of highly flexible white opaque vinyl or similar material of dimensions similar to the like dimensions of the upper envelope layer **15** and lower envelope layer **17**. The spacer **21** is provided with circular apertures **23** and **25** which are positioned in alignment with the die LEDs **5** and **7** and the die photodetector **11**, respectively, as shown in FIG. 3. Polyvinylchloride (PVC) has been found to be a suitable material for the envelope **19** and spacer **21**.

A supporting spine member **27** may be disposed within the envelope **19** between the flexible printed circuit board substrate **3** and the lower envelope layer **17**. The spine member **27** is preferably formed from a malleable form sustaining material such as a thin sheet of metal. In the preferred embodiment of the invention, an aluminum spine having a shape congruent to that of the flexible printed circuit board substrate **3** is employed.

Presence of the spine **27** permits the sensor appliance **1** to be held in place on the body member, e.g., finger, simply by bending and pressing the spine member **27** about the member into a snug fit. The form sustaining property of the spine **27**, thereafter, maintains the sensor appliance **1** in place on the body member. In the absence of the spine member **27**, it is necessary to use an adhesive or an external holding or clamping device to maintain the sensor appliance **1** in proper position without movement to enable stable measurement to be accomplished.

The outer edges of the envelope **19**, including upper envelope layer **15** and lower envelope layer **17**, and spacer **21** are hermetically sealed about their peripheries **22**. In the preferred embodiment of the invention the seal is accomplished by RF welding. The envelope **19** is also sealed about the cable **13** so that the flexible printed circuit board substrate **3** is encapsulated in a hermetically impervious environment.

The result is a sensor appliance **1** which can be readily cleaned or disinfected by wiping the surface with alcohol or another suitable sterilizing solution. The structure of the sensor appliance **1** is robust and allows repeated use. Conformability about small body members is enhanced by the low profile and reduced rigidized length of the sensor appliance **1**.

When the malleable spine **27** is employed, it enhances ambient light rejection in addition to supporting and maintaining the sensor appliance **1** in place on the body member. Moreover, with the spine member **27** holding the sensor appliance **1** in place, controlled movement of the sensor appliance **1** can be made to obtain the position of most favorable signal response and the position will be maintained with stability after the sensor appliance **1** is released and while an additional adhesive or non-adhesive wrap is applied, if required. The perimeter weld allows for a relatively small sensor appliance **1** since a large surface area is not required to hold the structure together and prevent delamination.

It is to be understood and appreciated that alterations, modifications and variations of and to the preferred embodiment described herein may be made without departing from the spirit and scope of the invention which is defined in the following claims.

What is claimed is:

1. A sensor appliance adapted for removable attachment to a living body for non-invasively producing signals indicative of a condition of the body and applying them to a monitoring or measuring device comprising:

an elongated flexible base comprising a form sustaining material for maintaining the shape of said base when bent about the surface of a body member in conformance therewith for retention thereon,

a sensor integrally bonded with a first surface of said base for stable disposition proximate said body member during retention thereon,

and a signal conductor connected to said sensor and adapted for connection to said monitoring or measuring device.

2. A sensor appliance according to claim 1 wherein said sensor comprises a die photodetector.

3. A sensor appliance according to claim 2 further comprising an energy source bonded to said base, said sensor producing a signal in response to said energy.

4. A sensor appliance according to claim 3 wherein said sensor is covered with a rigid encapsulating material transparent to the energy emitted by said energy source.

5. A sensor appliance according to claim 4 wherein said rigid encapsulating material comprises a glob-top epoxy.

6. A sensor appliance according to claim 4 wherein said sensor comprises means responsive to light having a wave length in the range of 660 nanometers to 940 nanometers and said transparent rigid encapsulating material comprises a substance transparent to light in said range.

7. A sensor appliance according to claim 1 wherein said base comprises a flexible substrate and a flexible, form sustaining spine comprising said material, and further comprising confining means for holding said substrate and said spine in close proximity.

8. A sensor appliance according to claim 7 wherein said sensor is bonded to said substrate with a thermally conductive surface bonding agent.

9. A sensor appliance according to claim 7 wherein said sensor is bonded to said substrate with an electrically conductive surface bonding agent.

10. A sensor appliance according to claim 9 wherein said surface bonding agent comprises a die attachment epoxy.

11. A sensor appliance according to claim 7 wherein said confining means comprises a flexible sealed envelope.

12. A sensor appliance according to claim 1 further comprising a rigid support mounted on a second surface of said base opposite said sensor.

13. A sensor appliance adapted for removable attachment to a living body for non-invasively producing signals indicative of body tissue content and applying them to a monitor or other measuring device comprising

an elongated flexible substrate adapted to be bent about the surface of a body member for conformance therewith and retention thereon,

a source of energy integrally bonded with a first area on a first surface of said substrate for transmitting energy to the proximate body tissue,

a sensor integrally bonded with a second area on said first surface of said substrate for stable disposition proximate said body member during retention thereon while receiving said energy transmitted by said energy source and affected by the proximate body tissue,

a flexible sealed envelope in which said substrate is disposed and

a signal conductor connected to said sensor and adapted for connection to said monitoring or measuring device.

14. A sensor appliance according to claim 13 further comprising a malleable spine disposed in said envelope.

15. A sensor appliance according to claim 14 wherein said malleable spine comprises a material opaque to said energy.

16. A sensor appliance according to claim 13 wherein said substrate is substantially U-shaped having an inner surface comprising said first surface, said energy radiating means and sensor means each being mounted on said inner surface in mutually facing relationship.

17. A sensor appliance according to claim 13 further comprising a flexible spacer disposed between said substrate and said envelope and having respective apertures in alignment with said energy source and said sensor for permitting transmission of said energy from said energy source through said cover, to the tissue and then through said envelope to said sensor.

* * * * *

United States Patent [19]

Takatani et al.

[11] **Patent Number: 4,867,557**

[45] **Date of Patent: Sep. 19, 1989**

[54] **REFLECTION TYPE OXIMETER FOR APPLYING LIGHT PULSES TO A BODY TISSUE TO MEASURE OXYGEN SATURATION**

[75] Inventors: **Setsuo Takatani, Hyogo; Kunio Awau; Masahiko Kanda, both of Osaka, all of Japan**

[73] Assignee: **Sumitomo Electric Industries, Ltd., Osaka, Japan**

[21] Appl. No.: **180,047**

[22] Filed: **Apr. 11, 1988**

[30] **Foreign Application Priority Data**

Apr. 9, 1987 [JP] Japan 62-87468

[51] **Int. Cl.**[4] **G01N 33/49**

[52] **U.S. Cl.** **356/41**; 128/633

[58] **Field of Search** 356/40, 41; 128/633

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,706,927	4/1955	Wood	356/41
3,638,610	2/1972	Lyles et al.	118/636
4,523,279	6/1985	Sperinde et al.	356/41 X

FOREIGN PATENT DOCUMENTS

51785	4/1977	Japan .
88778	8/1978	Japan .
160445	9/1987	Japan .

Primary Examiner—Vincent P. McGraw

Attorney, Agent, or Firm—W. G. Fasse; D. H. Kane, Jr.

[57] **ABSTRACT**

A reflection type oximeter comprises light emitting diodes (**11** to **16**) as first to sixth light sources which emit first and second beams of a wavelength involving a change in absorption due to a change an oxygen saturation of hemoglobin in blood of a tissue of a living body, third and fourth beams of another wavelength involving no change in absorption, and fifth and sixth beams of a further wavelength involving a relatively small change in absorption due to changes in a quantity of hemoglobin an oxygen saturation. The beams ae applied to the body tissue and the beams of the first to sixth light sources reflected by the body are received by a light receiving element (**17**). Intensities of the beams emitted from the light emitting diodes are set to predetermined levels and the intensities of the beams received by the light receiving element are evaluated by a CPU (**23**). Based on a predetermined function, the quantity of hemoglobin and of the oxygen saturation of the body tissue are evaluated. The resulting values are displayed on a display portion (**26**) and printed by a printer (**27**).

12 Claims, 7 Drawing Sheets

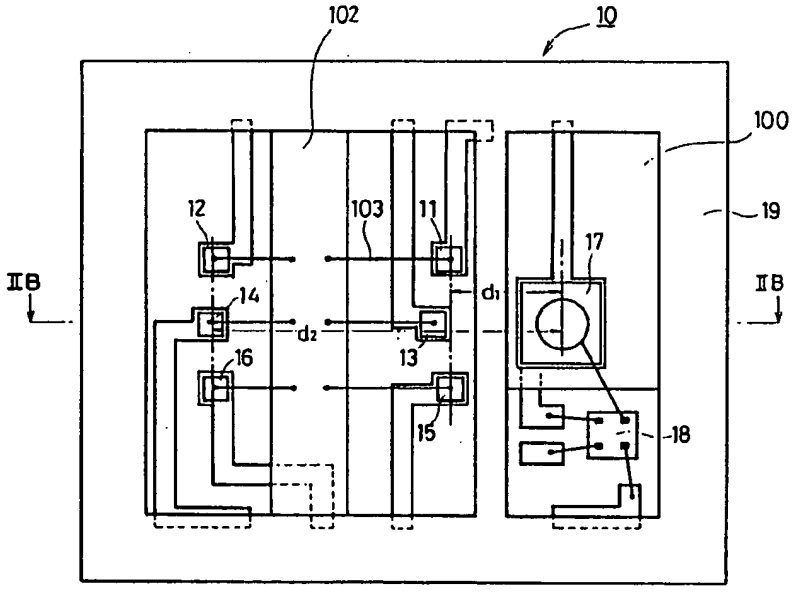
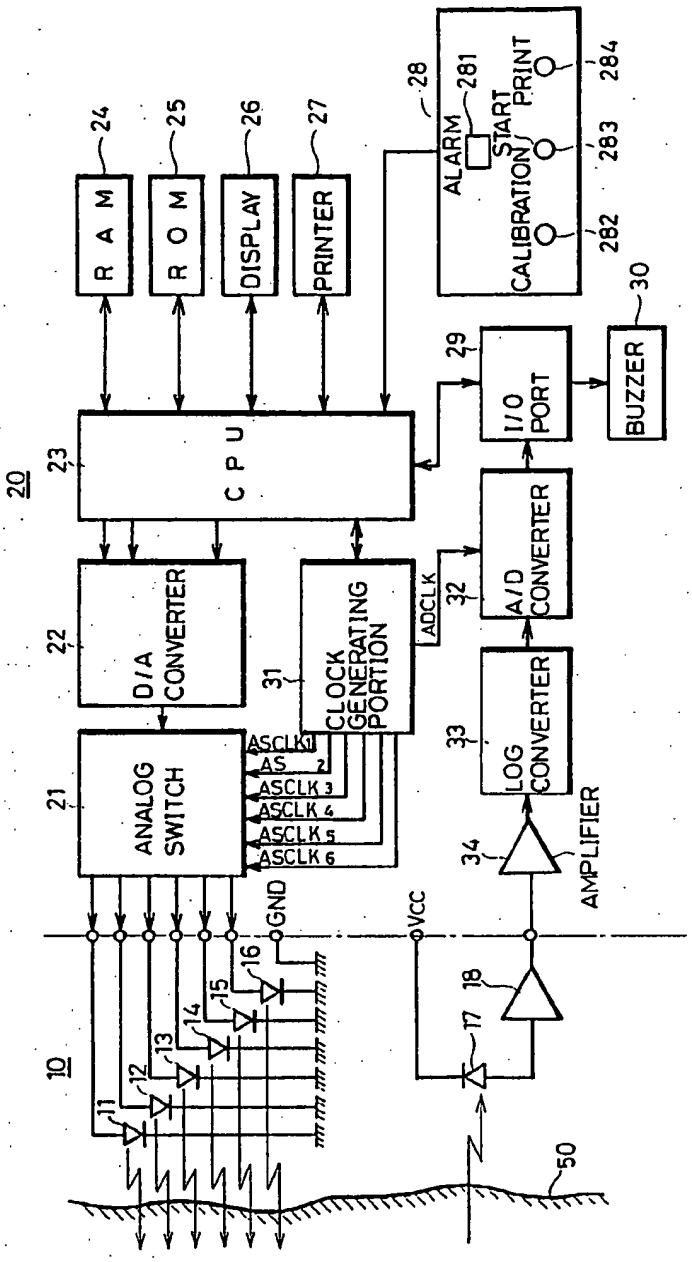


FIG.1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A/D CONVERTER
LOG CONVERTER
AMPLIFIER
ANALOG SWITCH
ADCLK
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AS 2
ASCLK 3
ASCLK 4
ASCLK 5
ASCLK 6
GND
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FIG.2A

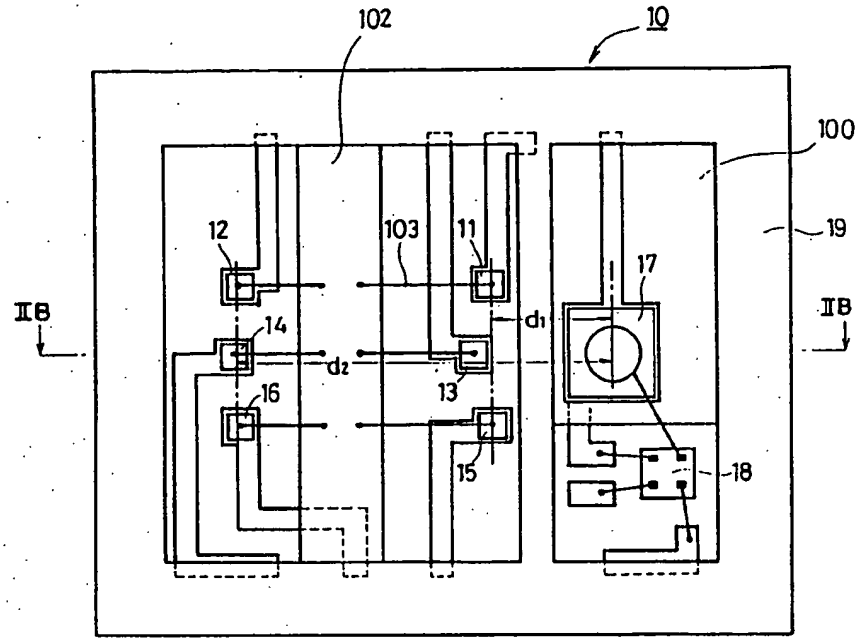
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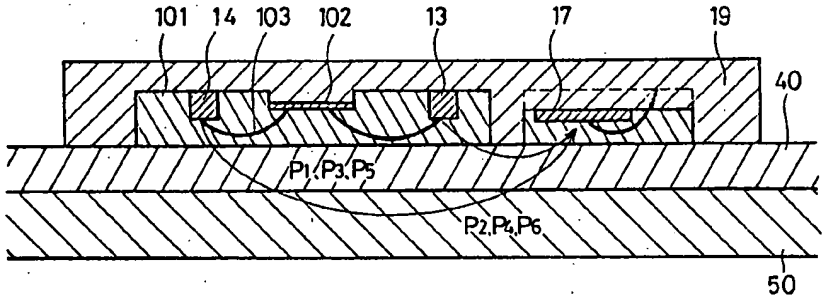
FIG.2B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P1,P3,P5
P2,P4,P6
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FIG.3

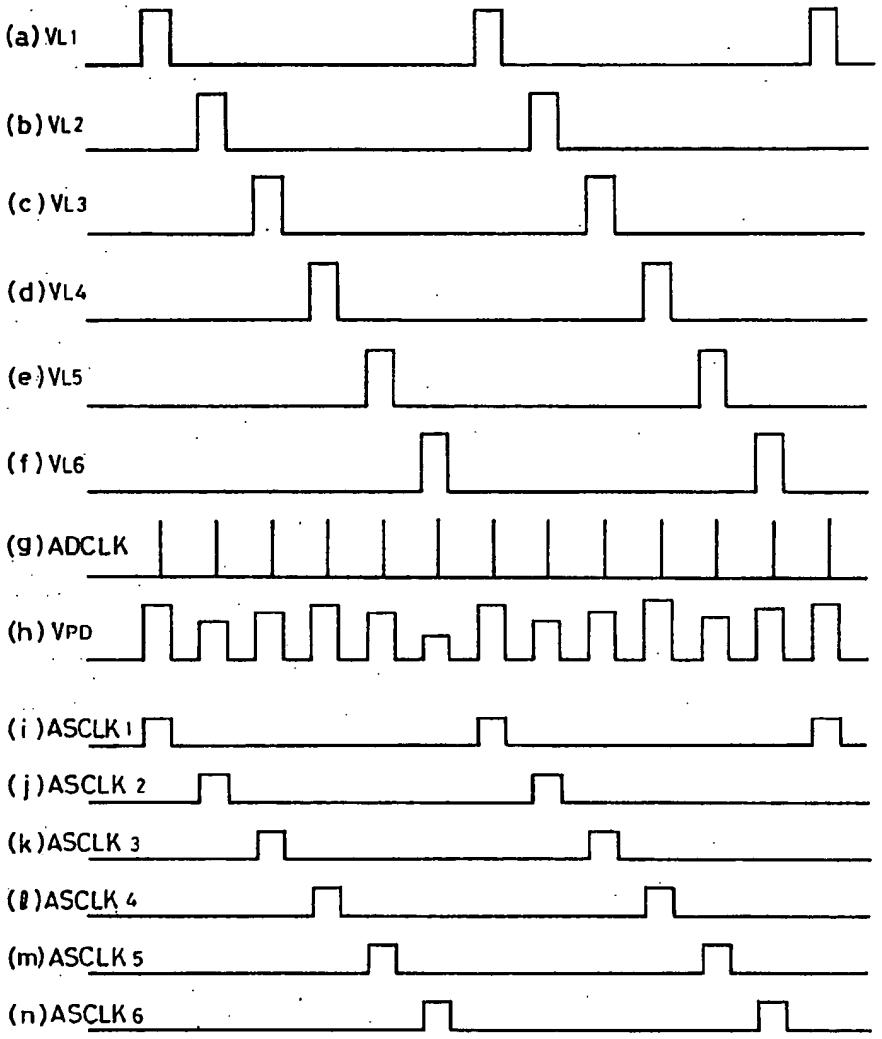
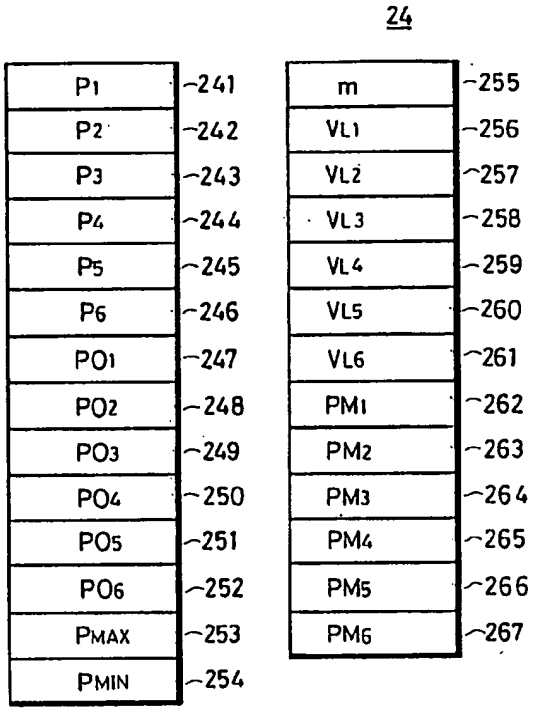


FIG.4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PM1
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FIG.5

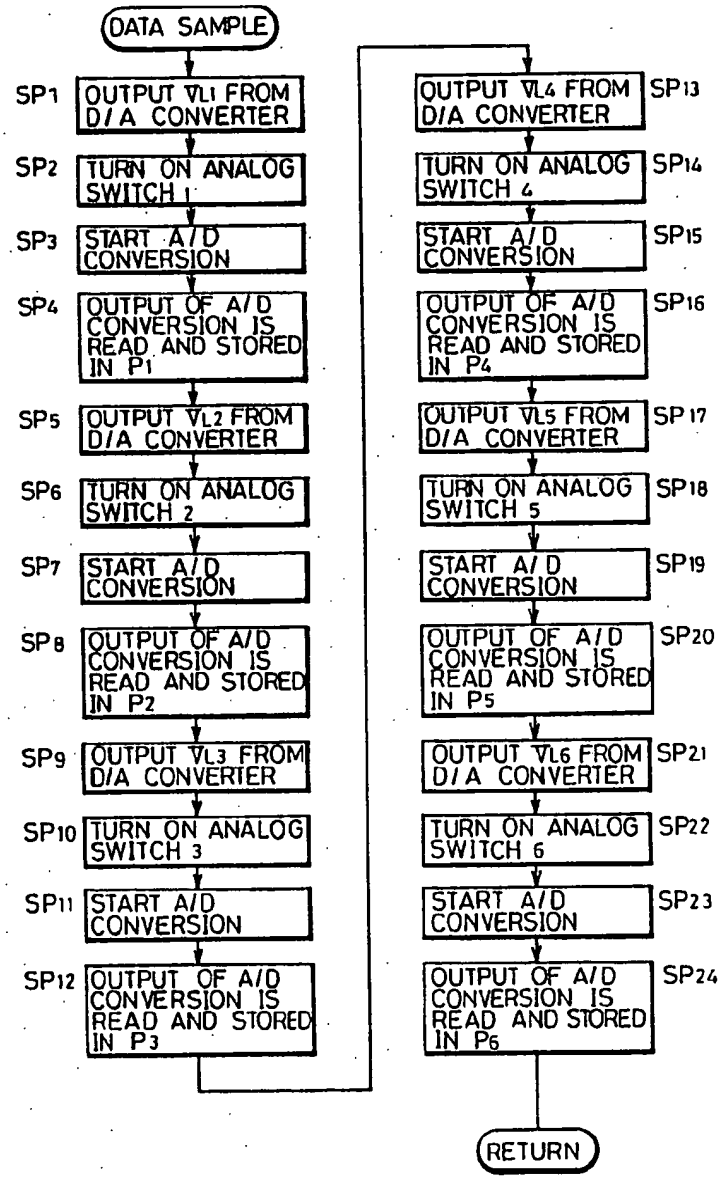


FIG.6

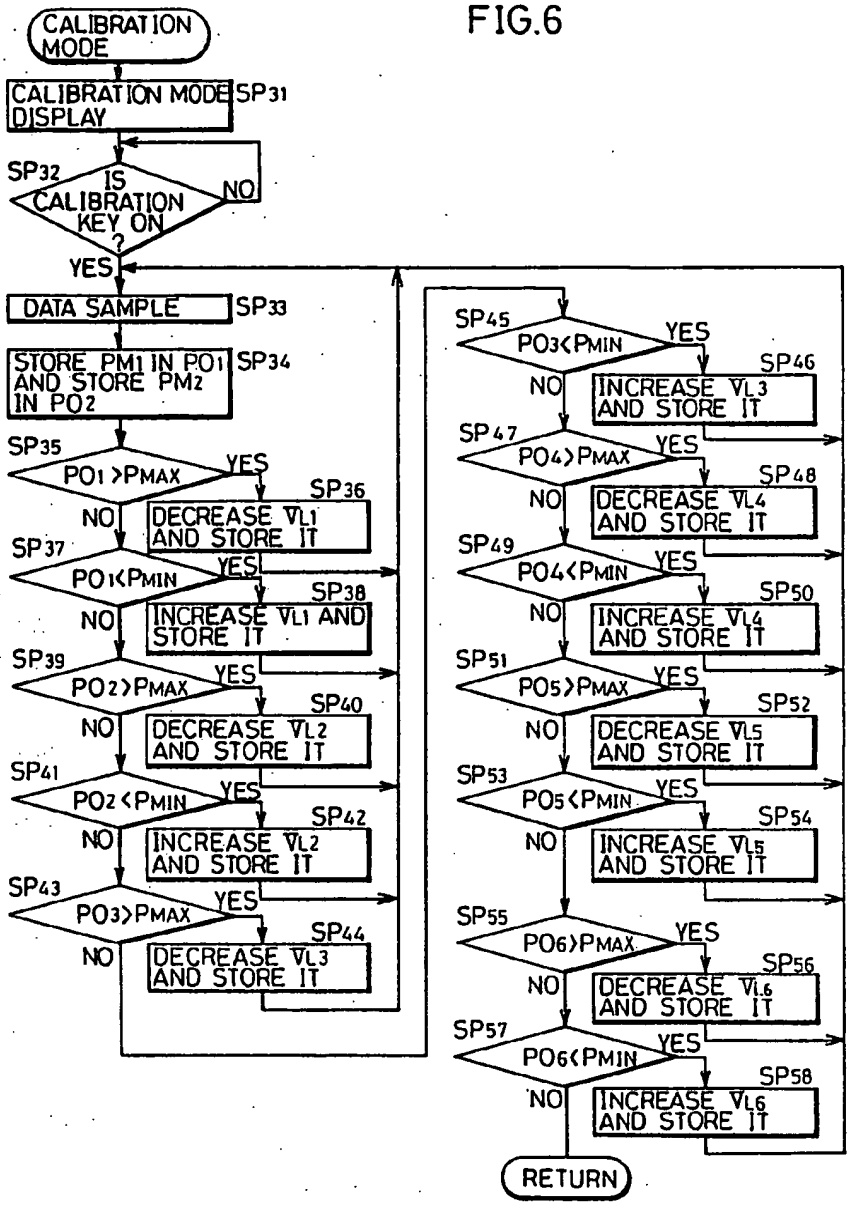
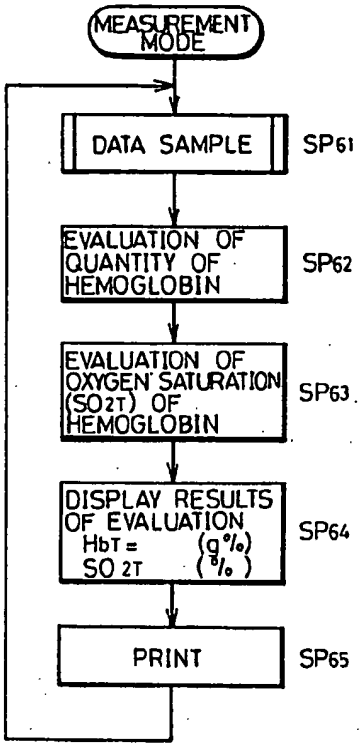


FIG.7


MEASUREMENT MODE
DATA SAMPLE
SP61
EVALUATION OF QUANTITY OF HEMOGLOBIN
SP62
EVALUATION OF OXYGEN SATURATION (SO_{2T}) OF HEMOGLOBIN
SP63
DISPLAY RESULTS OF EVALUATION
Hb_T = (g%)
SO_{2T} (%)
SP64
PRINT
SP65

REFLECTION TYPE OXIMETER FOR APPLYING LIGHT PULSES TO A BODY TISSUE TO MEASURE OXYGEN SATURATION

FIELD OF THE INVENTION

The present invention relates to a reflection type oximeter. More particularly, the present invention relates a reflection type oximeter in which light pulses are applied to a tissue of a living body to measure oxygen saturation or the like in an non-invasive manner based on light reflected from said body.

BACKGROUND INFORMATION

A conventional optical oximeter is known as an apparatus for measuring oxygen saturation in arterial blood based on light transmitted through the finger, the ear or the like of a person to be examined, when light is applied thereto.

U.S. Pat. No. 2,706,927 discloses an apparatus for evaluating oxygen saturation based on measured values of absorbance of each of two different wavelengths in two states, i.e., a state in which the ear is pressed and congested and a state in which the pressure on the ear is relieved. The measured value in the congested state is baased on only absorbant components other than the blood and the measured value in the non-pressed state is based on both of the blood and the other absorbant elements. Therefore, the absorbance of only the blood should be indicated by camparing values read or measured in the two states. However, the precision of the measured value would be lowered because all the blood cannot be removed by pressing the ear and because optical connections between the ear and the optical apparatus vary. In addition, the influence of the absorbant components due to differences in color of the skin and the skin thickness, for example, can differ considerably dependent on the respective persons to be examined and, accordingly, it is necessary to effect a calibration for each person or each measured value.

U.S. Pat. No. 3,638,610, discloses how to avoid described defect by utilization of measured values of absorbance based on a plurality of wavelengths of light. Similarly to all conventional apparatuses, the good result obtained by the apparatus of U.S. Pat. No. 3,638,610 depends on an increase of perfusion in the living body examined. For that reason, the perfusion in the living body is made to be as close as possible to the arterial blood as possible. The perfusion can be increased artificially until an accurate result can be obtained. However, such method is often unfavorable or very difficult dependent on the conditions of the person examined.

Japanese Patent Laying-Open Gazette No. 88778/1978 discloses an oximeter having the below described features. Light of one wavelength and light of another wavelength are applied successively to the fingers, the earlobes or other parts of a living body. The known oximeter comprises photodetector means which generates a first electric signal proportional to part of the light of a wavelength absorbed in such part of the body and generates a second electric signal proportional to part of light of another wavelength in that body part. When the heart sends a larger quantity of blood to the artery tissue than during a heart pause, a larger quantity of blood exists in that part of the body and accordingly the lights of the two wavelengths are more attenuated than during the heart pause. Consequently, the first and second electric signals have peaks of the maximum and minimum values in one pulse period of the heart. The difference of the maximum and minimum peak values entirely depends a pulsating current of blood, while the pulse period is not at all influenced by the absorbant component which attenuates light by a given quantity.

However, a measurement is not permitted in a body part where an artery blood current is not obtained or in a body part where a cuvette necessary for detection of transmitted light cannot be attached.

Japanese Patent Laying-Open No. 51785/1977 discloses a reflection type oximeter which can be attached to a part of a living body without a cuvette as is required in the above described examples. However, the oximeter of Japanese Patent Publication 51785/1977 is used in principle for detecting of a pulsation component and accordingly it is impossible to make measurements if the pulsation component is not obtained.

Japanese Patent Laying-Open No. 160445/1984 discloses an oximeter wherein a pulsation component of the artery blood current is detected as a change of a transmitted light component of the light applied to the tissue, whereby an oxygen saturation in the arterial blood is measured. Consequently, the following disadvantages are involved.

Such an oximeter is incapable of making measurements in a part or a state where a pulsation component does not exist. The measured results are only an oxygen saturation degree and a quantity of hemoglobin and the apparatus is incapable of measuring a tissue oxygen saturation including and providing information on venous blood serving as an index representing metabolism of the tissue. Since the oximeter of Japanese Patent Publication 160445/1984 utilizes transmitting and absorbing functions of the mechanism, it can be attached only to a part used as an optical cell. In addition, since a transmission path of light is not clearly known, it is not clear to which part (volume) the detected information pertains. Further, noise occurs due to sway or vibration of the sensor.

SUMMARY OF THE INVENTION

Therefore, it is a primary object of the present invention to provide a reflection type oximeter which can overcome the above described disadvantages and which is capable of evaluating functions of the lung or the heart of a living body or a state of oxygen supplied to the tissue of the body, and capable of continuously monitoring conditions of a patient for a long period.

The present invention performs its operation by the combination of the following features. First and second beams of a wavelength subjected to a change in absorbance due to a change in oxygen saturation of hemoglobin in blood of tissue of a living body, third and fourth beams of another wavelength not subjected to any change in absorbance, and fifth and sixth beams of a further wavelength subjected to a relatively small change in absorbance due to changes in a quantity of hemoglobin and oxygen saturation, are applied to the tissue of the body, and light receiving means receives the first to sixth beams reflected from the tissue of the body. Intensities of the respective outputs of the light receiving means are evaluated and, based on a predetermined function, the quantity of hemoglobin in the tissue is calculated and the result of the calculation is outputted.

Consequently, the present invention makes it possible to avoid various problems encountered in the conventional non-invasive type oximeters, such as the ability of measuring in a body part where a pulsation component does not exist, measurements limited only to oxygen saturation in an artery, noise due to sway or vibration of a sensor, and the ability of measuring without an optical cuvette because of an optical transmission method. Accordingly, the oximeter of the present invention is capable of evaluating lung functions, heart functions, the state of oxygen supplied to tissue, and other data in examinations of anesthesiology, dermatology, pediatrics etc., and is also capable of continuously monitoring conditions of a patient for a long period.

In a preferred embodiment of the present invention, a calibration mode and a measurement mode can be selected and when the calibration mode is selected, a voltage to be applied to light source means is set so that the intensity of light emitted from the light source means is within a predetermined range.

According to the above-mentioned preferred embodiment of the present invention, the intensity of light emitted from the light source means is calibrated prior to measurement and a quantity of hemoglobin in the tissue of the body can be measured more accurately.

In another preferred embodiment of the present invention, assuming that intensities of the first, second, third, fourth, fifth and sixth beams reflected from the tissue are P1, P2, P3, P4, P5 and P6, the quantity of hemoglobin in the tissue is calculated by:

$$C1\ [\log (P3/P4)]^2 + C2 \log (P3/P4) + C3$$

where C1, C2 and C3 are correction values.

In addition, in a further preferred embodiment of the present invention, the light source means is formed by first to sixth light sources emitting the first to sixth beams, respectively, and the first, third and fifth light sources are located at positions distant from the center of the light receiving means by a predetermined distance d1, while the second, fourth and sixth light sources are located at positions distant from the center of the light receiving means by a predetermined distance d2, with a relation of $d1 < d2$ being maintained.

In another aspect of the present invention, first and second beams of a wavelength subjected to a change in absorbance due to a change in oxygen saturation of hemoglobin in the blood of the tissue of a living body, third and fourth beams of another wavelength not subjected to any change in absorbance, and fifth and sixth beams of a further wavelength subjected to a relatively small change in absorbance due to a change in oxygen saturation are applied to the tissue of the body and the first to sixth beams relected therefrom are detected, whereby intensities of the respective beams are evaluated and the oxygen saturation of the tissue is evaluated based on a predetermined function.

Consequently, according to this aspect of the invention, it becomes possible to measure the oxygen saturation in a body part not containing a pulsation component, which could not be measured in a conventional apparatus.

These objects and other objects, features, aspects and advantages of the present invention will become more apparent from the following detailed description of the present invention when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic block diagram of an embodiment of the present invention.

FIG. 2A is a plan view of a sensor portion shown in FIG. 1.

FIG. 2B is a sectional view taken along the line IIB—IIB shown in FIG. 2A.

FIG. 3 is a timing chart for detection of the intensities of beams reflected from an object to be measured, said beams having wavelengths λ1, λ2 and λ3.

FIG. 4 is a diagram showing data stored in a RAM shown in FIG. 1.

FIGS. 5 to 7 are flowcharts for explaining the actual operation of the embodiment of the present invention. Particularly, FIG. 5 shows a data sample subroutine, FIG. 6 shows a calibration mode, and FIG. 7 shows a measurement mode.

DESCRIPTION OF THE PREFERRED EMBODIMENTS AND OF THE BEST MODE OF THE INVENTION

First referring to FIGS. 2A and 2B, a principle of the present invention will be described. A sensor portion 10 comprises a first light source 11, a second light source 12, a third light source 13, a fourth light source 14, a fifth light source 15, a sixth light source 16, a light receiving element 17, and a preamplifier 18, which are integrally formed as a unitary body disposed on a black ceramic substrate 100. Light emitting diodes are used as the first to sixth light sources 11 to 16. The light emitting diodes 11 and 12 emit light of a wavelength λ1 (for example, 660 nm), the absorbance of which is considerably changed due to a change in the oxygen saturation in the blood. The light emitting diodes 13 and 14 emit light of a wavelength λ2 (for example, 805 nm), the absorbance of which undergoes substantially no change due to a change in the oxygen saturation of hemoglobin. The light emitting diodes 15 and 16 emit light of a wavelength λ3 (for example, 940 nm), the absorbance of which is changed to a relatively small extent due to changes in the oxygen saturation of hemoglobin and the quantity of hemoglobin. The light emitting diodes 11, 13 and 15 are located at positions apart from the center of the light receiving element 17 by a distance d1 and the light emitting diodes 12, 14 and 16 are located at positions apart from the center of the light receiving element 17 by a distance d2, with a relation of $d1 < d2$ being maintained.

There is provided a light interception wall 19 which surrounds the light sources 11 to 16, the light receiving element 17, and the preamplifier 18. The wall 19 separates the light sources 11 to 16 from the light receiving element 17 for preventing an incidence of external light on the light receiving element 17 and to prevent direct application of light from the light sources 1 to 16 to the light receiving element 17. The partition wall which separates the light sources 11 to 16 from the light receiving element 17 has a thickness of 0.5 mm or less for example and a height of about 0.8 mm for example. The wall 19 also prevents resin material 101 (of epoxy, urethane, silicone or the like) introduced onto the light sources 11 to 16 and the light receiving element 17 from flowing outside the wall. A relay electrode 102 is formed between the light sources 11, 13 and 15 and the light sources 12, 14 and 16. The relay electrode 102 comprises a copper film formed on the black ceramic substrate 100 and it distributes electric power supplied

from outside the sensor portion 10, to the respective light sources 11 to 16. Electric current is supplied from the relay electrode 102 to the respective light sources 11 to 16 through boding wires 103 and the current is fed back through a printed circuit for example formed on the black ceramic substrate 100.

A detailed description of the transmission of light in the sensor portion 10 thus constructed, is given for example in a document "Photon Diffusion Theory" published by Takaya et al. This theory summarized as follows. The sensor portion 10 is attached to a part of a human body, for example a fingertip, and the light sources 11 to 16 are caused to emit beams successively, so that a plurality of light sources may not emit beams concurrently. The beams emitted by the light sources 11, 13 and 15 near the light receiving element 17 are diffused and reflected in the tissue of the body and reach the light receiving element 17 as shown by arrows in FIG. 2B. Intensities of the beams received in the light receiving element 17 are represented as P1, P3 and P5. The beams emitted by the light sources 12, 14 and 16 distant from the light receiving element 17 are also diffused and reflected in the tissue of the body and reach the light receiving element 17. Intensities of the beams thus received are represented as P2, P4 and P6. The intensities P1, P3 and P5 and the intensities P2, P4 and P6 are obtained through different transmission paths and include different types of information. Let us consider the paths of the reflected beams referring to FIG. 2B. Transmission of the beams is specifically applied according to the above described photon diffusion theory and the intensities of P2, P4 and P6 represent information from a deeper part than the information of the intensities of P1, P3 and P5. Therefore, as shown in FIG. 2B, it is assumed that a region sampled by the intensities of the received beams P1, P3 and P5 is a first layer 40, that a region sampled by the intensities of the received beams P2, P4 and P6 is a second layer 50, and that characteristics given at the time of transmission of the beams in the respective layers are represented as $\alpha 11$ and $\alpha 12$. It is assumed in this case that the characteristics $\alpha 11$ and $\alpha 12$ depend on the transmission, absorption or scattering of the beams from the light sources, hemoglobin existing in the tissue and the like. If intensities of the beams emitted from the light sources 11 and 12 are represented as I1 and I1', respectively, the received light amounts P1 and P2 are represented in the following simplified manner:

$$P1 = I1 \cdot \alpha 11$$

$$P2 = I1' \cdot \alpha 11 \cdot \alpha 12 \quad (1)$$

If a ratio between the intensities of the received beams P1 and P2 is considered, it is represented by the following equation (2).

$$\frac{P2}{P1} = \frac{I1' \cdot \alpha 11}{I1 \cdot \alpha 11 \cdot \alpha 12} \quad (2)$$

If I1 = I1', that is, the intensities of the emitted beams are equal, the above stated equation (2) is represented by the following equation (3)

$$P2/P1 = 1/\alpha 12 \quad (3)$$

According to the equation (3), the component of the first layer 40 is removed. This means that only the component of the second layer 50 is detected according to the equation (3). If, for example, the distance d1 (between the light sources 11, 13 and 15 and the light receiving element 17) is set to obtain, as the component of the first layer 40, information of a capillary layer liable to cause disturbance in the bloodstream when it is pressed by the sensor attached and the distance d2 (between the light sources 12, 14 and 16 and the light receiving element 17) is set to obtain, as the component of the second layer 50, information of a bottom of blood hardly subjected to disturbance when it is pressed by the attached sensor, an artifact due to disturbance in the bloodstream, which was a problem to be solved in the prior art, can be removed.

At the same time, skin may be considered as being included in the first layer 40 and the problem of an individual difference such as a difference in the color of the skin, can be also dissolved by applying the above described principle.

Similarly, the above described principle is also applied to the two groups of light sources 13, 14, 15 and 16 having the different wavelengths $\lambda 2$ and $\lambda 3$ of light and the following equations are obtained.

$$\frac{P4}{P3} = \frac{I2' \cdot \alpha 21}{I2 \cdot \alpha 21 \cdot \alpha 22} \quad (4)$$

$$\frac{P6}{P5} = \frac{I3' \cdot \alpha 31}{I3 \cdot \alpha 31 \cdot \alpha 32} \quad (5)$$

In addition, if I2' = I2 and I3' = I3, the following equations are obtained.

$$\frac{P4}{P3} = \frac{1}{\alpha 22}, \frac{P6}{P5} = \frac{1}{\alpha 32} \quad (6)$$

Thus, it is understood that the problem of an artifact influenced by a disturbance in the bloodstream the problem of an individual difference in the skin, can be removed in the same manner as in the case of the wavelength $\lambda 1$.

It is indicated by Takayama et al. for example that the quantity of hemoglobin (Hb_T) in the tissue of the living body is obtained in the following manner.

$$Hb_T = C1[\ln(1/R)]^2 + C2[\ln(1/R)] + C3 \quad (7)$$

where R is an intensity of light reflected from the tissue, having a wavelength not causing any change the absorbance due to a change in the oxygen saturation of hemoglobin, and wherein C1, C2 and C3 are coefficients set at the time of calibration. Now, if the principle of the present invention is applied to the above described equation (7), the following equation (8) can be considered.

$$Hb_T = D1\ [\log (P3/P4)]^2 + D2\ [\log (P3/P4)] + D3 \quad (8)$$

where D1, D2 and D3 are coefficients set at the time of calibration.

From the above-mentioned equation (8), it becomes possible to determine and measure the quantity of hemoglobin (Hb_T) in the tissue of the living body by removing the artifact caused by a disturbance in the bloodstream due to the pressure of the sensor attached, or due to the individual difference in the color of the skin.

The oxygen saturation (So_2T) of the tissue is expressed by the following equation (9).

$$S_{02T} = A - B \times \log\left(\frac{P1/P2}{P5/P6}\right) / \log\left(\frac{P3/P4}{P5/P6}\right) \quad (9)$$

where A and B are coefficients set at the time of calibration. In this case also, the theory represented by the above-mentioned equation (6) is applied and it becomes possible to make stable measurements by removing the artifact caused by a disturbance in the bloodstream by pressure of the attached sensor of by the individual difference of the color of the skin.

In the following, the embodiment of the present invention will be described based on the above described principle.

Referring to FIG. 1 showing an embodiment of the invention with a reflection type oximeter comprising a sensor portion 10 described above with reference to FIGS. 2A and 2B, and a measurement processing portion 20. The sensor portion 10 comprises the first to sixth light sources 11 to 16, the light receiving element 17 and the preamplifier 18 as described above. The light sources 11 to 16 are driven by the measurement processing portion 20 so that they emit light successively by pulse operation.

The measurement processing portion 20 comprises a central processing unit (CPU) 23 as evaluation means. The CPU 23 supplies, to a D/A converter 22, data for controlling intensities of light pulses emitted from the light sources 11 to 16. The D/A converter 22 converts the data to an analog signal, which is supplied to an analog switch 21. The analog switch 21 comprises six switching elements which are operated by clock signals ASCCKL1, 2, 3, 4, 5 and 6 supplied by a clock generator 31, so that an output of the D/A converter 22 is supplied to the light sources 11 to 16. An output of the light receiving element 17 is supplied to an amplifier 34 through the preamplifier 18, so that it is amplified. An output of the amplification is supplied to a LOG converter 33 so as to be logarithmically converted. An output of the LOG converter 33 is sampled by an A/D converter 32 and outputted as a digital signal. The digital signal is supplied to the CPU 23 through an I/O port 29. The A/D converter 32 receives a clock signal ADCLK from the clock generator 31. The I/O port 29 is connected with a buzzer 30. The buzzer 30 is used to issue an alarm when a result is measured that considerably deviates from a normal value.

Further, the CPU 23 is connected with a RAM 24, a ROM 25, a display portion 26, a printer 27, and an operation portion 28. The RAM 24 stores various data as shown in FIG. 4 as described later. The ROM 25 stores programs based on flowcharts shown in FIGS. 5 to 7. The display portion 26 displays a result of evaluation of the CPU 23 and the printer 27 prints the result of evaluation.

The operation portion 28 includes an alarm LED 281, a calibration key 282, a start key 283 and a print key 284. The alarm LED 281 displays an alarm when a result of calculation has a low reliability. The calibration key 282 is used to set a calibration mode. The start key 283 instructs a start of a measuring mode and the print key 284 instructs a printout of the result of calculation.

FIG. 3 is a timing chart for detection of intensities of the beams of the wavelengths λ1, λ2 and λ3 transmitted through an object to be measured. FIG. 4 is a diagram showing data stored in the RAM shown in FIG. 1. FIGS. 5 to 7 are flowcharts for explaining an actual operation of the embodiment of the present invention. Particularly, FIG. 5 shows a data sample subroutine; FIG. 6 shows the calibration mode; and FIG. 7 shows the measurement mode.

Referring now to FIGS. 1 to 7, an actual operation of the embodiment will now be described. First, the steps SP1 to SP24 shown in FIG. 5 are procedures sampling the intensities of the beams of the wavelengths λ1, λ2 and λ3 transmitted through the object to be examined and storing the sampled intensities in areas 241 to 246 of the RAM 24.

More specifically, in the step SP1, the CPU 23 reads data of a drive voltage V_{L1} of the first light source 11 stored in a storage area 256 of the RAM 24 shown in FIG. 4 and supplies the data to the D/A converter 22. The D/A converter 22 converts the data of the voltage to an analog signal and supplies it to the analog switch 21. The analog switch 21 receives the clock signal ASCLK1 as shown at (i) of FIG. 3, from the clock generator 31. In the step SP2, the analog switch 21 is turned on in response to the clock signal ASCLK1 and supplies, to the first light source 11, the analog voltage V_{L1} as converted by the D/A converter 22. Then, the first light source 11 emits light of an intensity corresponding to the drive voltage V_{L1} and applies it to the object 50 to be examined.

The emitted light is reflected by the object 50 and is received by the light receiving element 17. The light receiving element 17 converts the received light to an electric signal and supplies it to the amplifier 34 through the preamplifier 18. The amplifier 34 amplifies the signal and supplies it to the LOG converter 33 so that it is logarithmically converted. The logarithmically converted voltage is supplied to the D/A converter 32. The clock signal ADCLK as shown in (g) of FIG. 3 is applied from the clock generator 31 to the A/D converter 32. Accordingly, in the step SP3, the A/D converter 32 converts the analog output of the LOG converter 33 to a digital output based on the clock signal ADCLK. The digital output is supplied to the CPU 23 through the I/O port 29. In the step SP4, the CPU 23 reads the output of the A/D conversion and stores it as P1 in the area 241 of the RAM 24.

Similarly, the CPU 23 reads data of a drive voltage V_{L2} of the second light source shown in (b) of FIG. 3 stored in the area 257 of the RAM 24 and supplies it to the analog switch 21 through the D/A converter 22. The clock signal ASCLK2 as shown in (j) of FIG. 3 is applied by the clock generator 31 to the analog switch 21. Accordingly, in the step SP6, the analog switch 21 is turned on based on the clock signal ASCLK2 to supply the drive voltage V_{L2} to the second light source 12. Then, the second light source 12 emits light of an intensity corresponding to the drive voltage V_{L2} and applies it to the object 50 to be examined. The emitted light of the wavelength λ1 is reflected by the object 50 and is received by the light receiving element 17.

The light receiving element 17 photoelectrically converts the received light and supplies it to the amplifier 34 through the preamplifier 18. The output of the amplifier 34 is logarithmically converted by the LOG converter 33 in the same manner as described above and is supplied to the A/D converter 32. In the step SP7, the A/D converter 32 starts an A/D conversion based on the clock signal ADCLK from the clock generator 31. An output of the A/D conversion is supplied to the CPU 23 through the I/O port 29. In the step SP8, the

CPU 23 reads the output of the A/D conversion and stores it as P2 in the area 242 of the RAM 24. Subsequently, the CPU 23 performs the operations steps SP9 to SP24, in which the CPU 23 drives the third to sixth light sources 13 to 16 based on data of the drive voltages V_{L3} to V_{L6} stored in the areas 258 to 261 of the RAM 24 and stores the data as P3 to P6 in the areas 243 to 246, respectively, based on the output of the light receiving element 17.

Now, the calibration mode shown in FIG. 6 will be described. The calibration mode is started when the power supply of the apparatus is turned on or when the operation performed in the measuring mode shown in FIG. 7 as described below is brought to an end. In the step SP31, the CPU 23 displays the calibration mode on the display portion 26. This display serves to indicate that the calibration mode is selected and it also provides an instruction to the operator for attaching the sensor portion 10. According to this instruction, the operator of the apparatus attaches the sensor portion 10 to the object 50 to be examined. Then, in the step SP32, the CPU 23 waits until the calibration key 282 is operated. When the calibration key 282 has been operated, the CPU 23 proceeds to step SP 33 to execute the data sample subroutine shown in FIG. 5.

The CPU 23 measures the data P1 to P6 m times and stores these data. Based on these data stored in the area 255 of the RAM 24 average light data PM1 to PM6 are obtained by averaging the stored data m times .The data PM1 to PM6 are stored in areas 262 to 267 of the RAM 24. Further, the CPU 23 stores the values of PM1 to PM6 in the areas 247 to 252 of the RAM 24 as PO1 to PO6 in the step SP34. Then, the CPU 23 executes the steps SP35 to SP57, in which the drive voltages V_{L1} to V_{L6} applied to the first to sixth light sources 11 to 16, are regulated so that PO1 to PO6 are set between the light data P_{MAX} and P_{MIN} ($P_{MAX} > P_{MIN}$) stored in the areas 253 and 254 of the RAM 24, respectively.

More specifically, in the step SP35, if PO1 is larger than P_{MAX}, the CPU proceeds to the step SP36 to set the drive voltage V_{L1} to a small value. Then, the steps SP33 and SP34 are executed again and it is determined in the step SP35 whether PO1 is larger than P_{MAX}. If PO1 is not smaller than P_{MAX}, the CPU 23 proceeds to the step SP37 to determine whether PO1 is smaller than P_{MIN}. If PO1 is smaller than P_{MIN}, the value of the drive voltage V_{L1} is increased in step SP38 and then the CPU 23 returns to the above-mentioned step SP33. These operations are repeated to regulate the drive voltage V_{L1} so that PO1 is set between P_{MAX} and P_{MIN}.

Subsequently, the operations of steps SP39 to SP58 are executed and the drive voltages V_{L2} to V_{L6} are regulated so that PO2 to PO6 are set between P_{MAX} and P_{MIN}. Then, the finally set drive voltages V_{L1} to V_{L6} are stored in the areas 257 to 261 of the RAM 24.

Then, the operator attaches the sensor portion 10 to a part to be examined, for example, a fingertip and operates the start key 283, whereby the CPU 23 proceeds to the measuring mode shown in FIG. 7. More specifically, in step SP61, the above described data sample subroutine shown in FIG. 5 is executed and P1 to P6 based on the light pulses received from the first to sixth light sources 11 to 16, reflected on the part to be examined, are stored in the areas 241 to 246 of the RAM 24. Then, the CPU 23 substitutes P3 and P4 stored in the areas 242 and 245 of the RAM 24 into the above-mentioned equation (8) and evaluates the quantity of hemoglobin Hb_T. Further, in step SP63, the CPU 23 substitutes P1, P2, P3, P4, P5 and P6 stored in the areas 241, 243, 244 and 246 of the RAM 24 into the above indicated equation (9) to evaluate the oxygen saturation S_{O2T} of the body tissue. The quantity of hemoglobin Hb_T and the oxygen saturation S_{O2T} of hemoglobin in the body tissue determined by the evaluation operations are displayed on the display portion 26. If the print key 284 is operated in this case, the results of the evaluation Hb_T and S_{O2T} are printed by the printer 27 in the step SP65. The buzzer 30 issues an alarm when the results of measurement become lower than predetermined levels when the patient is being monitored.

As described above, according to the embodiment of the present invention, light pulses of the wavelength the absorbance of which is considerably changed by a change in the oxygen saturation of hemoglobin in the blood of the body tissue and the light pulses the absorbance of which is not changed, and the light pulses the absorbance of which is changed to a small extent by changes in the quantity of hemoglobin and the oxygen saturation are applied at the predetermined levels from the positions near the light receiving portion and the position a little distant therefrom, and the light pulses reflected through the tissue are detected, whereby the oxygen saturation of hemoglobin in the blood of the tissue and the quantity of hemoglobin are evaluated based on the predetermined functions. Consequently, it becomes possible to solve various problems that are present in the conventional non-invasive oximeters, such as the inability of measuring in a part where a pulsation component does not exist, or measurements limited only to the oxygen saturation in an artery, or the occurrence of noise due to sway or vibration of a sensor, or the inability of measuring without an optical cuvette for an optical transmission method. Therefore, the present invention makes it possible to evaluate lung functions, heart functions, conditions of oxygen supplied to the body tissue, and other data in examinations of anesthesiology, dermatology, pediatrics, or the like, and to continuously monitor a patient over a long period of time.

Although the present invention has been described and illustrated in detail, it is clearly understood that the same is by way of illustration and example only and is not to be taken by way of limitation, the spirit and scope of the present invention being limited only by the terms of the appended claims.

What is claimed is:

1. A reflection type oximeter comprising: beam source means including first to sixth beam sources (11 to 16) for emitting first to sixth beams and applying said beams to a living body tissue, wherein first and second beams have a wavelength involving a change in absorbance due to a change in an oxygen saturation of hemoglobin in blood of said body tissue, wherein third and fourth beams have another wavelength involving no change in absorbance, and wherein fifth and sixth beams have a further wavelength involving a relatively small change in absorbance due to changes in a quantity of hemoglobin and in an oxygen saturation, beam receiving means for detecting said first, second, third, fourth, fifth and sixth beams reflected from said tissue, wherein said first, third and fifth beam sources are located at positions distant from a center of said beam receiving means by a predetermined distance d1, and wherein said second, fourth and sixth beam sources are located at positions distant from the center of said beam receiving means by a predetermined distance d2, with a relation

of d1<d2 being maintained, evaluation means for evaluating intensities of said first, second, third, fourth, fifth and sixth beams reflected by said body tissue based on an output of said beam receiving means and for evaluating the quantity of hemoglobin in said body tissue based on a predetermined function, and output means (26, 27) for outputting results of the evaluation of said evaluating means.

2. The reflection type oximeter of claim 1, further comprising mode selection means (282, 283) for selecting between a calibration mode wherein a calibration is performed to set the intensities of the beams emitted from said beam source means within predetermined ranges, and a measuring mode wherein a quantity of hemoglobin in said body tissue is evaluated by said evaluation means.

3. The reflection type oximeter of claim 2, further comprising voltage setting means (21, 22) for setting a voltage to be applied to said beam source means in response to selection of the calibration mode by said mode selection means, to cause the intensities of the first to sixth beams emitted from said beam source means to be within said predetermined ranges.

4. The reflection type oximeter of claim 1, further comprising means (23) for calculating an average value of signals of each of said first to sixth beams received by said beam receiving means, said average being calculated a plural number of times, said evaluation means including means for evaluating the quantity of hemoglobin in said body tissue based on said average value and a predetermined function.

5. The reflection type oximeter of claim 1, wherein said evaluation means comprises means for evaluating the quantity of hemoglobin in said body tissue by the expression:

$$C1[\log (P3/P4)]^2+C2 \log (P3/P4)+C3$$

wherein P1, P2, P3, P4, P5 and P6 are the intensities of the first, second, third, fourth, fifth and sixth beams reflected from said body tissue, respectively, and C1, C2 and C3 are correction values.

6. A reflection type oximeter comprising: beam source means (11 to 16) including first to sixth beam sources for emitting first to sixth beams and applying said beams to a living body tissue, wherein first and second beams have a wavelength involving a change in absorbance due to a change in an oxygen saturation of hemoglobin in blood of said body tissue, wherein third and fourth beams have another wavelength involving no change in absorbance, and wherein fifth and sixth beams have a further wavelength involving a relatively small change in absorbance due to changes in a quantity of hemoglobin and in an oxygen saturation, beam receiving means (17) for detecting said first, second, third, fourth, fifth and sixth beams reflected from said tissue, wherein said first, third and fifth beam sources are located at positions distant from a center of said beam receiving means by a predetermined distance d1, and wherein said second, fourth and sixth beam sources are located at positions distant from the center of said beam receiving means by a predetermined distance d2, with a relation of d1<d2 being maintained, evaluation means (23) for evaluating intensities of said first, second, third, fourth, fifth and sixth beams reflected by said body tissue based on an output of said beam receiving means and evaluating the oxygen saturation of said body tissue based on a predetermined function, and output means (26, 27) for outputting results of the evaluation by said evaluation means.

7. The reflection type oximeter of claim 6, further comprising mode selection means for selecting between a calibration mode wherein a calibration is performed to set the intensities of the beams emitted from said beam source means within predetermined ranges, and a measuring mode wherein an oxygen saturation of said body tissue is evaluated by said evaluation means.

8. The reflection type oximeter of claim 7, further comprising

voltage setting means (21, 22) for setting a voltage to be applied to said beam source means in response to selection of the calibration mode by said selection means, to cause the intensities of said first to sixth beams emitted from said beam source means to be within said predetermined ranges.

9. The reflection type oximeter of claim 6, further comprising means (23) for calculating an average value of signals of each of said first to sixth beams received by said beam receiving means, said average being calculated a plural number of times, said evaluation means including means (23) for evaluating the oxygen saturation of said tissue based on said average value and said predetermined function.

10. The reflection type oximeter of claim 6, wherein evaluation means comprises means for evaluating the oxygen saturation of said body tissue by the expression:

$$A - B \cdot \log\left(\frac{P1/P2}{P5/P6}\right) / \log\left(\frac{P3/P4}{P5/P6}\right)$$

wherein P1, P2, P3, P4, P5 and P6 are the intensities of the first, second, third, fourth, fifth and sixth beams reflected from said body tissue, respectively, and A and B are correction values.

11. A reflection oximeter comprising: beam source means including first to sixth beam sources for emitting first to sixth beams and applying said beams to a living body tissue, wherein first and second beams have a wavelength involving a change in absorbance due to a change in an oxygen saturation of hemoglobin in blood of said body tissue, wherein third and fourth beams having another wavelength involving no change in absorbance, and wherein fifth and sixth beams have a further wavelength involving a relatively small change in absorbance due to changes in a quantity of hemoglobin and in an oxygen saturation, beam receiving means for detecting said first, second, third, fourth, fifth and sixth beams reflected from said tissue, wherein said first, third and fifth beam sources are located at positions distant from a center of said beam receiving means by a predetermined distance d1, and wherein said second, fourth and sixth beam sources are located at positions distant from the center of said beam receiving means by a predetermined distance d2, with a relation of d1<d2 being maintained, setting means for setting intensities of the beams emitted from said beam source means to predetermined levels, evaluation means for evaluating intensities of said first, second, third, fourth, fifth and sixth beams reflected by said body tissue based on an output of said beam receiving means and for evaluating the quanity of hemoglobin and the oxygen saturation of said body tissue based on a predetermined function, and

output means for outputting results of the evaluation by said evaluation means.

12. The reflection type oximeter of claim 11, wherein said intensities of the first, second, third, fourth, fifth and sixth beams reflected from said body tissue are represented as P1, P2, P3, P4, P5 and P6, respectively, wherein said evaluation means evaluate the quantity of hemoglobin of said tissue by the expression:

$$C1[\log (P3/P4)]^2+C2 \log (P3/P4)+C3$$

where C1, C2 and C3 are correction values, and wherein said evaluation means evaluates the oxygen saturation of said tissue by the expression:

$$A - B \cdot \log\left(\frac{P1/P2}{P5/P6}\right)/\log\left(\frac{P3/P4}{P5/P6}\right)$$

where A and B are correction values.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,867,557

DATED : September 19, 1989

INVENTOR(S) : Setsuo Takatani; Kunio Awazu; Masahiko Kanda

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page:

In [75] replace the second inventor's name to read as follows:
--Kunio Awazu--.

In [57] Abstract, line 4, after "change" insert --in--;
line 10, before "an" insert --and--, replace "ae" by --are--.

Claim 10, line 1 of claim 10, after "wherein" insert --said--.

Claim 11, line 8 of claim 11, replace "having" by --have--;

Signed and Sealed this

Fourteenth Day of August, 1990

Attest:

Attesting Officer

HARRY F. MANBECK, JR.

Commissioner of Patents and Trademarks

US006256525B1

(12) **United States Patent**
Yang et al.

(10) **Patent No.: US 6,256,525 B1**
(45) **Date of Patent: Jul. 3, 2001**

(54) **CATHETER DISTAL END ASSEMBLIES WITH BONDED SURFACE COATINGS**

(75) Inventors: **Yi Yang**, San Francisco; **Josef Koblish**, Sunnyvale; **Russell B. Thompson**, Los Altos; **David K. Swanson**, Mountain View, all of CA (US)

(73) Assignee: **EP Technologies, Inc.**, San Jose, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/573,447**

(22) Filed: **May 16, 2000**

Related U.S. Application Data

(63) Continuation of application No. 09/032,707, filed on Feb. 27, 1998, now Pat. No. 6,097,976.

(51) **Int. Cl.**[7] **A61E 5/04**

(52) **U.S. Cl.** **600/373**; 600/374; 606/41

(58) **Field of Search** 606/32, 34, 35–41, 606/45–50; 600/373, 374, 380, 381, 395; 427/2.1, 2.12, 58; 604/264–266, 523, 524; 607/122–124

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,568,660	3/1971	Crites et al.	128/2
3,635,212	1/1972	Watanabe et al. .	
3,910,008	10/1975	Johnson	53/112 A
4,402,319	9/1983	Handa et al. .	
5,304,120	4/1994	Crandell et al.	604/52
5,507,744	4/1996	Tay et al.	606/41
5,508,899	4/1996	Fan et al.	604/96
5,531,715	7/1996	Engelson et al.	604/265
5,804,318	9/1998	Pinchuk et al. .	
5,954,702	9/1999	Lai et al.	604/283
5,991,650 *	11/1999	Swanson et al.	600/374

FOREIGN PATENT DOCUMENTS

WO97/45156 4/1997 (WO) .

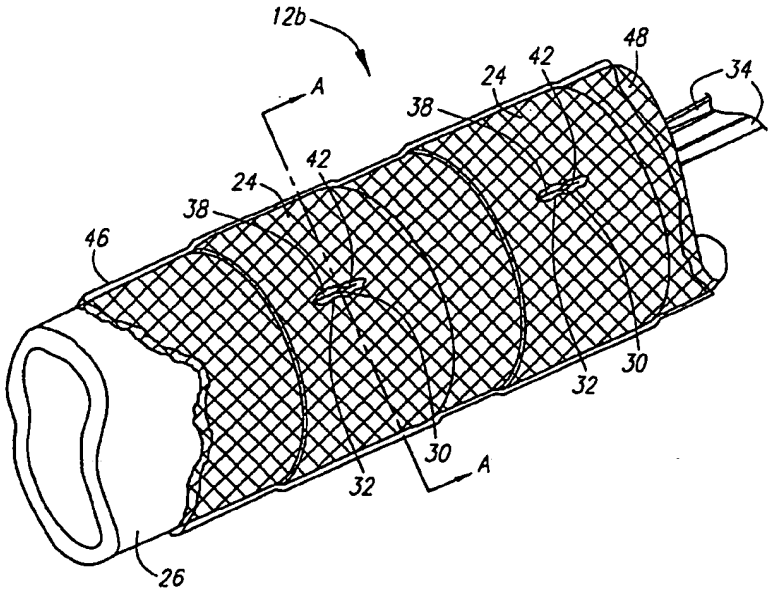
* cited by examiner

Primary Examiner—Linda C. M. Dvorak
Assistant Examiner—David M. Ruddy
(74) *Attorney, Agent, or Firm*—Lyon & Lyon LLP

(57) **ABSTRACT**

Invasive medical catheters with distal end assemblies having a protective surface coating bonded thereto are constructed by applying a hydrophilic primer to at least a portion of a tubular polymer body. The primer coating chemically bonds to the polymer substrate by developing covalent bonding or cross linking with the substrate. A plurality of printed electrode elements are then formed on the polymer body, e.g., by a pad printing process. Once the primer coating is bonded to the polymer body, the assembly is coated with a regenerated cellulose layer, e.g., by a viscose process well known in the art. The primer coating, already bonded to the catheter body, is then bonded with the regenerated cellulose at an elevated temperature. After curing, the polymer body, primer coating and regenerated cellulose layer become a single composite material, thereby preventing the regenerated cellulose coating from any movement relative to the polymer body, and providing a secure protective layer over the electrodes.

14 Claims, 4 Drawing Sheets



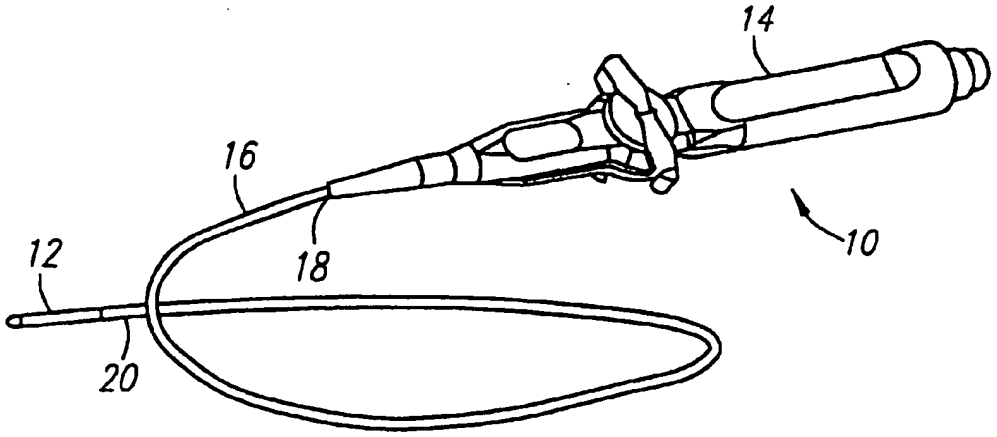


FIG. 1

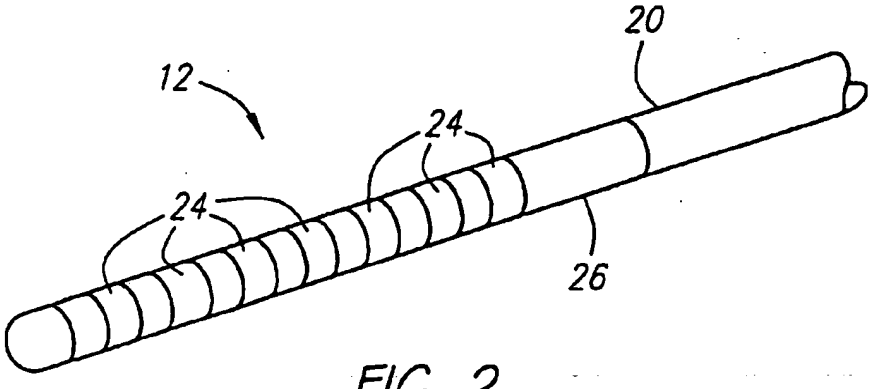


FIG. 2

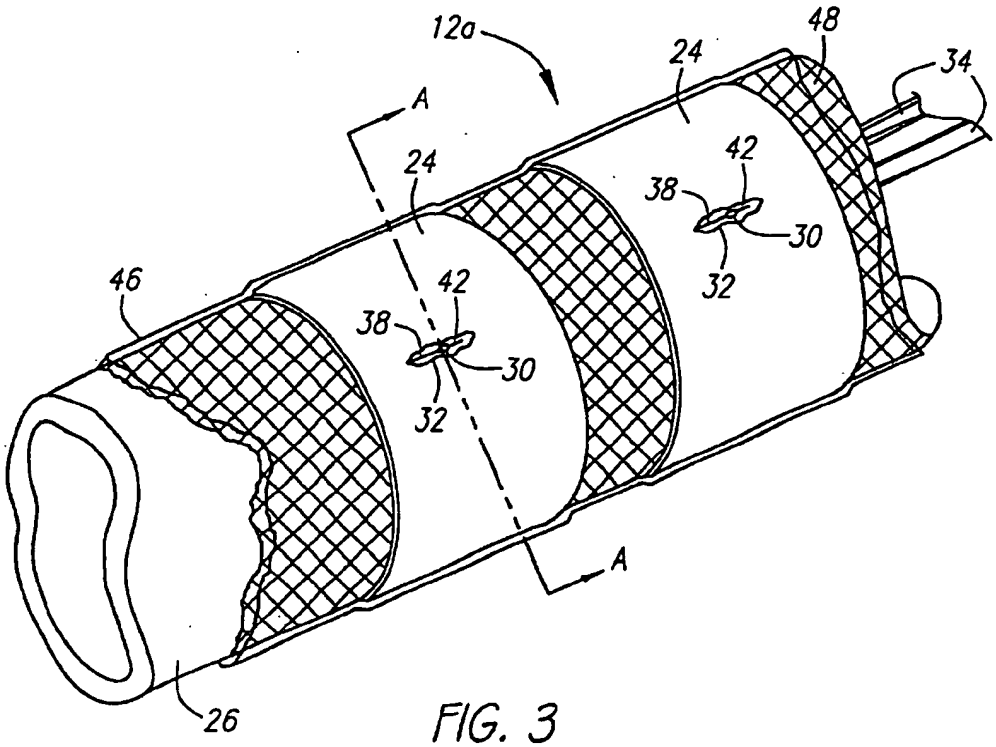


FIG. 3

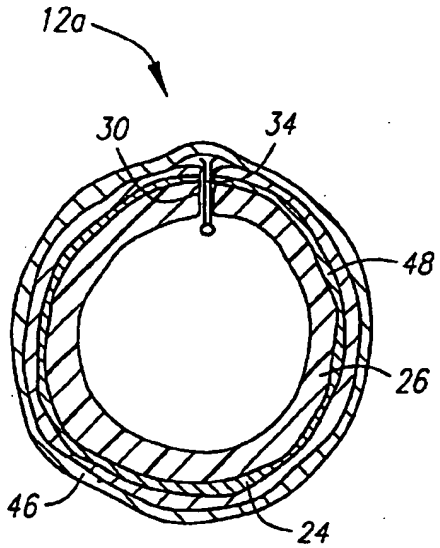


FIG. 4

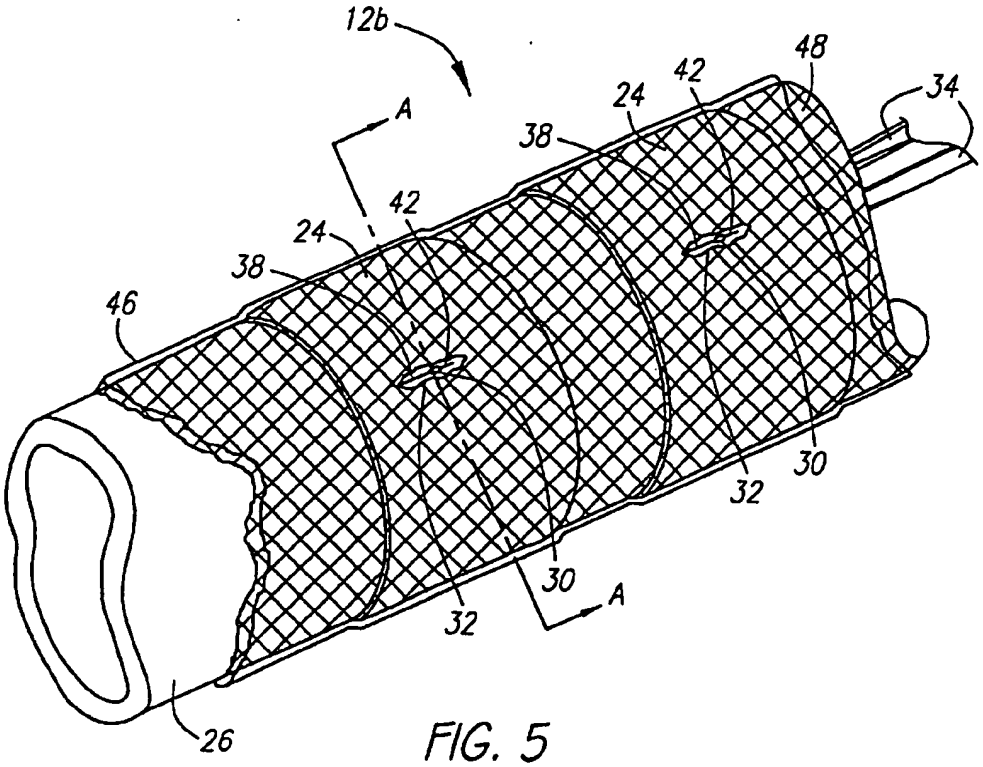


FIG. 5

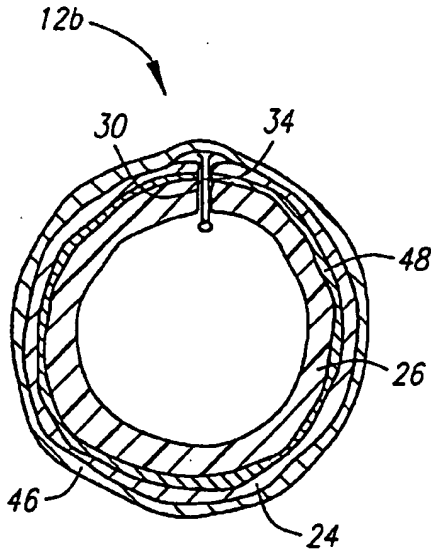


FIG. 6

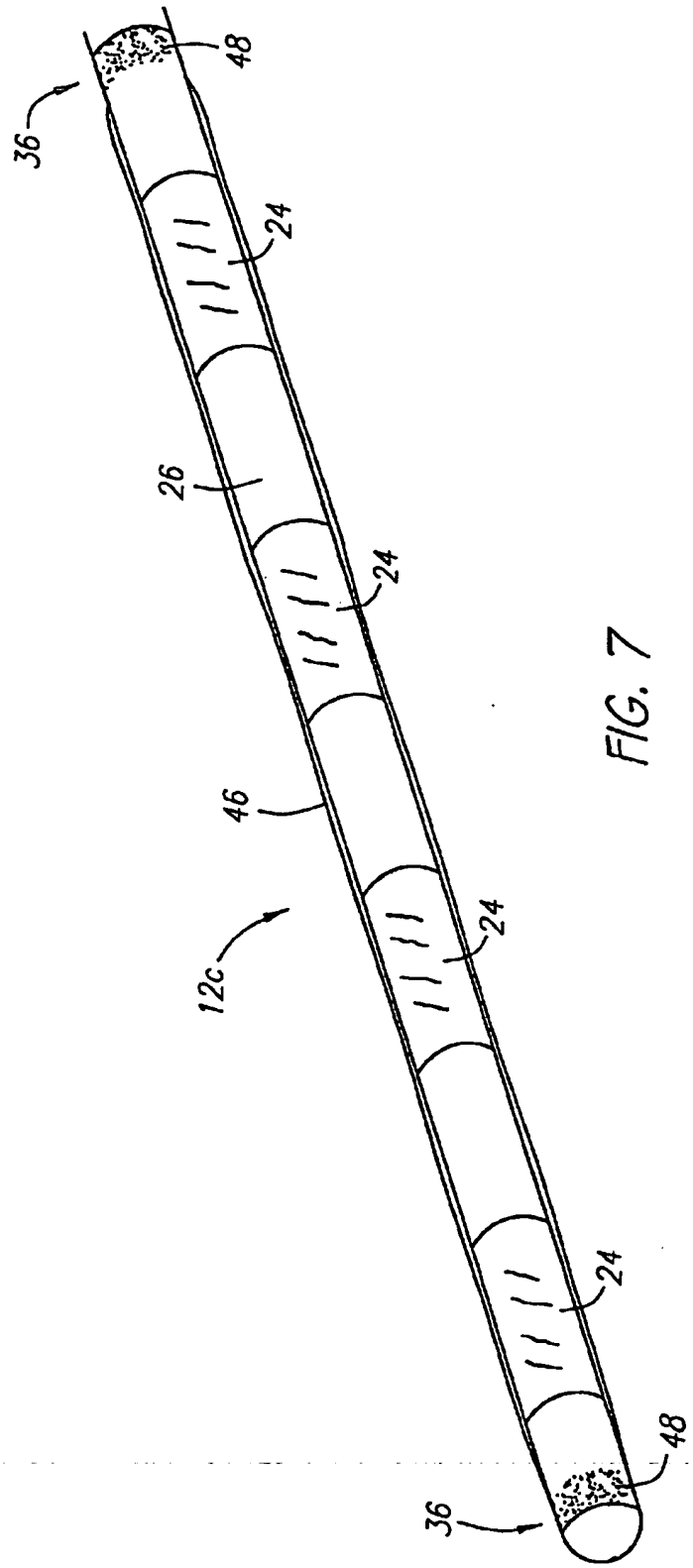


FIG. 7

CATHETER DISTAL END ASSEMBLIES WITH BONDED SURFACE COATINGS

This application is a continuation of Ser. No. 09/032,707 Feb. 27, 1998 U.S. Pat. No. 6,097,976.

FIELD OF THE INVENTION

The present invention relates generally to invasive diagnostic and therapeutic medical catheter assemblies and, more particularly, to distal end surface coatings used on such assemblies.

BACKGROUND

Conventionally, external components located on invasive medical catheters, such as an electrode or thermocouple, are manually placed on the catheter body—e.g., in the form of wound coil or a conductive band. The components are typically held in position with an adhesive, a process which is relatively time consuming and expensive.

One notable problem with this construction is that if an external component is not properly fit onto the catheter body, small openings and crevices at the edges of the component may be formed, allowing for the ingress and retention of bodily fluids or tissue during use. Additionally, this traditional catheter-electrode construction can result in undesirably high electrode edge effects caused by the sharp transition between the conductive electrode band and the immediately adjacent non-conductive catheter body.

Further, because the electrode components come into direct contact with a patient's blood stream and body tissues during use, non-biocompatible (i.e., toxic) materials otherwise having advantageous characteristics for use in an externally mounted electrode, including silver or lead, cannot be used.

Therefore, a need has existed for an improved external electrode constructions for invasive medical catheters.

Such improvements are disclosed and described in U.S. Pat. No. 5,991,650, which is fully incorporated herein by reference for all it discloses and describes. As disclosed therein, a metal-based conductive ink is used to form exterior electrodes on a non-conductive polymer catheter tubing by processes such as pad printing, vapor deposition, ion beam assisted deposition, electroplating or other printed circuit manufacturing processes. Preferred ink materials include a silver/silver chloride filled polyurethane composite ink that is flexible and highly electrically conductive after the polyurethane is cured. The printed ink electrodes are then covered with an electrically conductive outer coating, preferably formed from a material comprising regenerated cellulose.

The regenerated cellulose coating secures the underlying electrode structures onto the catheter, while still enabling electrical contact between the electrodes and surrounding body tissue structures. One advantage of using regenerated cellulose for the protective coating is that regenerated cellulose is ion-permeable, thereby allowing ionic transfer of electrical energy from the electrodes into the patient's bloodstream and/or body tissue, while preventing macromolecules, such as blood proteins, from contacting the printed electrode material during use.

Additionally, because the regenerated cellulose surface coating produces a smooth outer surface to the distal end assembly, lead wires and temperature sensing devices can be bonded to the exterior surface of electrodes and then coated to produce a smooth outer surface, thus providing a simple,

inexpensive manufacturing method for the attachment of such components to the electrodes.

In particular, the regenerated cellulose coating acts as a mechanical barrier between the catheter components, such as electrodes, preventing ingress of blood cells, infectious agents, such as viruses and bacteria, and large biological molecules such as proteins, while providing electrical contact to the human body. As a result the electrodes can be made using more efficient processes (such as pad printing) that have been previously rejected due to lack of robustness when directly exposed to bodily tissues on a catheter surface.

The regenerated cellulose coating also acts as a biocompatible barrier between the catheter components and the human body, whereby the components can now be made from materials that are somewhat toxic (such as silver or copper), because the diffusional distance to tissues is increased substantially, and because a lower percentage of the metallic surface is exposed (both directly and indirectly) to the tissue.

In addition, coating electrodes with regenerated cellulose decreases the effect of convective cooling on the electrode during RF energy delivery. That is, since regenerated cellulose is a poor thermal conductor when compared to metal, the effect of convective cooling by blood flowing past the regenerated cellulose coated electrodes is diminished. This provides better control for the lesion-generating process because the hottest tissue temperature is closer to the ablation electrode.

Furthermore, the regenerated cellulose coating decreases the edge effects attributed to delivering RF energy to the electrode having sharp transition between the conductive electrode and insulating catheter tubing. The current density along the electrode and power density within tissue are more uniform, which reduces the incidence and severity of char and/or coagulum formation. The more uniform current density along the axis of the catheter also results in a more uniform temperature distribution at the electrode, which decreases the requirement for precise placements of the temperature sensors at the ablation electrodes.

Notably, intimate contact between the regenerated cellulose coating and the conductive electrodes on the catheter body is required to ensure reliable pacing, electrogram sensing, or ablation through the microporous structure of the regenerated cellulose coating. While the regenerated cellulose coating closely conforms to the catheter body, e.g., like a skin, it does not actually adhere to the polymers commonly used to make catheters, such as, e.g. polyether block amides (PEBAs). Nor does it adhere to metal-based printed ink materials. Instead, a mechanical fit of the regenerated cellulose "jacket" on the distal end of the catheter is relied upon.

Thus, if the distal end of the catheter is aggressively torqued or twisted, the regenerated cellulose jacket can at times "barber pole" or become axially wrinkled or blistered, resulting in a loss of direct contact of the coating and the underlying electrode structure. This can result in poor, intermittent, or even loss of electrical contact with the electrode. This compromised electrode contact can result in noisy recordings, inconsistent pacing thresholds, and unpredictable (and therefore uncontrollable) ablation conditions, depending upon the particular application.

Further, if the catheter is introduced through a close-fitting introducer (e.g., such as a pre-shaped guide sheath), the regenerated cellulose coating can become stretched axially relative to the underlying catheter body structure.

Because there is no conductive fluid such as saline between the electrode and regenerated cellulose coating, the electrical path can become intermittent or open where the two materials become separated.

Thus, for reasons of durability, consistent signal quality, pacing capabilities and ablation, it would be beneficial to improve upon the disclosure of U.S. patent application Ser. No. 08/879,343, and provide a coherent composite assembly for protecting the distal portion of the finished catheter device.

SUMMARY OF THE INVENTION

The present invention provides invasive medical catheters with distal end assemblies having a protective surface coating bonded thereto.

In an exemplary preferred embodiment, a base primer is applied over a non-conductive thermoplastic elastomer polymer body. The primer chemically bonds to the polymer body substrate by developing covalent bonding or cross linking with the substrate. A plurality of printed electrode elements are then formed on the polymer body, e.g., by a pad printing process. Once the primer coating is bonded to the polymer body, the entire assembly is coated with a solubilized cellulose derivative solution. The solubilized cellulose derivative is then converted back into a pure cellulose structure by a regeneration process, such as viscose process which is well known in the art.

The primer, already bonded to the polymer body, is then bonded to the regenerated cellulose by heat treating at an elevated temperature. After curing, the polymer body, primer coating and regenerated cellulose layer become a single composite material, thereby preventing the regenerated cellulose coating from any movement relative to the polymer body.

In alternate preferred embodiments, the primer may be applied over the top of the printed electrodes. In this case, a selected primer will preferably have a significantly lower electrical resistivity, so as to not interfere with the electrical conductivity of the electrodes.

In further alternate preferred embodiments, a standard adhesive, such as cyanoacrylate or epoxy, may be used in lieu of the base primer. Also, the primer or adhesive coating may be applied only to selected portions of the polymer body, e.g., on the non-conductive areas between electrodes, or only at end points of the distal end assembly.

Other objects and features of the present invention will become apparent from consideration of the following detailed description of preferred embodiments, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate both the design and utility of the present invention, in which similar elements in different embodiments are referred to by the same reference numbers for purposes of ease in illustration, wherein:

FIG. **1** is a perspective view of a catheter device provided with a distal end external electrode assembly;

FIG. **2** is a perspective view of the distal end assembly of the catheter device of FIG. **1**;

FIG. **3** is an enlarged, partially cut-away view of a first preferred distal end assembly for the catheter device of FIG. **1**;

FIG. **4** is a cross-sectional view taken along lines A—A of FIG. **3**;

FIG. **5** is an enlarged, partially cut-away view of a second preferred distal end assembly for the catheter device of FIG. **1**;

FIG. **6** is a cross-sectional view taken along lines A—A of FIG. **5**;

FIG. **7** is a perspective view of a distal end assembly of further alternate distal end catheter assembly.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. **1–2**, an exemplary catheter device **10** generally includes a handle **14** and an elongate tubular catheter body **16**. The catheter body **16** has a proximal end **18** engaging the handle **14** and a distal end **20** engaging a distal end assembly **12**. The distal end assembly **12** includes a non-conductive tubing **26** having a plurality of external conductive electrodes **24** formed thereon.

By way of example, the catheter device **10** may be a therapeutic instrument for use in an ablation procedure, wherein the distal end electrodes **24** would be configured for creating lesion patterns in internal body tissue. By way of alternate example, the catheter device **10** may be a diagnostic instrument for use in detecting the location of aberrant electrical pathways in a patient's myocardial tissue, wherein the distal end electrodes **24** would be configured for detecting electrical activity in body tissue.

The distal end tubing **26** of the distal end assembly **12** is preferably formed from a non-conductive thermoplastic elastomer, such as polyether block amides (PEBA), and may be extruded to provide a substantially smooth outer surface as shown. Alternatively, the outer surface of the distal body portion **26** may include a longitudinal channel, skive and the like (not shown) to facilitate assembly of the electrodes thereon.

In alternate preferred embodiments, the distal end assembly **12** can be formed on the distal end portion **18** of the elongate catheter body **16**—i.e., wherein the distal end tubing **26** is part of the distal elongate catheter **16**.

For purposes of illustration, the distal end assembly **12** of FIGS. **1–2** is a "generic" embodiment of the more specific preferred distal end assemblies disclosed and described in FIGS. **3–7**.

Referring to FIG. **3**, in a first preferred distal end assembly **12*a***, a primer coating **48** is applied over the surface of the distal end tubing **26** prior to formation of the electrodes **24**. By way of example, the primer coating **48** may be applied over the distal end assembly **12*a*** by dipping or spraying the distal end tubing **26** in or with a commercially available base primer, until a finished thickness of no more than about 0.0005 inch is obtained.

The selected primer may contain from about 85% wt to 95% wt, and preferably about 91% wt to 93% wt polyester-polyurethane aqueous dispersion such as Bayhydrol PR240™, and 5% wt to 15% wt, and preferably about 4% wt to 6% wt polyfunctional aziridine crosslinker such as Crosslinker CX-100™. Because it underlies the electrodes **24**, the selected primer coating **48** should preferably have a relatively high electrical resistivity—e.g., more than about 10^5 ohm-cm at a range of 0.1 to 500 kHz.

The primer coating **48** is then cured, for example, by heating the coated distal end assembly **12*a*** (e.g., between 35° C. to 65° C. for 1 to 2 hours), or exposing it to high intensity ultraviolet light, causing it to bond to the distal end tubing **26**. In particular, the primer coating **48** bonds to the distal end tubing **26** by developing a covalent bond or cross linking with the thermoplastic elastomer.

After the primer **48** is cured, the electrodes **24** are formed at predetermined locations on the primer-coated distal end assembly **12***a*. The electrodes **24** are preferably longitudinally spaced along the distal end tubing **26**, such that non-conductive areas of the distal end tubing **26** remain between consecutive electrodes.

The electrodes **24** may be formed using a variety of methods, such as those described in the above-incorporated U.S. Pat. No. 5,991,650. In one preferred embodiment, the electrodes **24** are formed from a conductive ink compound, such as a silver-based conductive polyurethane ink, which is pad printed onto the distal end tubing **26**. Alternatively, to increase their radiopacity, the electrodes **24** may be formed by multiple layers of different ink compounds (not shown). For example, the electrodes **24** may have a tungsten-filled polyurethane ink bottom layer for radiopacity and a silver-filled polyurethane ink top layer for electrical conductivity. Other metal-based conductive ink compounds, such as platinum-based or copper-based epoxies may also be used to form the electrodes **24**.

As best seen in FIG. **4**, a small opening **30** is provided through the distal end tubing **26** and cured primer coating **48** at each electrode location **24**, through which an insulated ribbon cable **34** carrying a lead wire **38** and thermocouple wires **42** extends from a proximal portion of the catheter device **10** (not shown). The insulation at the ends of the lead wire **38** and thermocouple wires **42** are stripped. The lead wire **38** is electrically connected to the surface of electrode **24**, e.g., by using a conductive adhesive supplemented by further application of conductive ink. A thermocouple is then formed by potting the thermocouple wires **42** to the outer surface of the distal end tubing **26** proximate the edge of the opening **30**, such that the resulting thermocouple is thermally coupled, but electrically isolated, from the electrode **24**.

Once the electrode construction is completed, including attachment of the respective lead and thermocouple wires **38** and **42**, a protective regenerative cellulose coating **46** is applied over the entire distal end assembly **12***a*—i.e., over both the primer coating **48** and the electrodes **24**. Several preferred processes for applying a regenerated cellulose coating or "jacket" over the distal end assembly **12***a* are disclosed and described in the above-incorporated U.S. Pat. No. 5,991,650.

After the regenerated cellulose coating is applied and cured, the distal end assembly **12** is again heat treated to facilitate bonding between the primer coating **48** and the regenerated cellulose coating **46**, preferably to between about 100° C. and about 110° C. for about one hour.

During this later heating process, a hydrogen bond is created between the hydroxyl group of the regenerated cellulose and the hydrogen molecule of the primer coating **48**. Because the primer coating **48** was originally cured prior to forming the electrodes **24**, adhesion between the primer **48** and regenerated cellulose **46** is achieved only where the primer **48** is not covered by the electrodes **24**.

In alternate preferred embodiments, the respective electrodes **24** may be formed over only part of the circumferential surface area of the distal end tubing **26**. In this instance, the bond formed between the respective regenerated cellulose coating **46** and tubing **26** would be continuous over that part of the catheter body not covered by the electrode surface. In the alternative, the regenerated cellulose coating **46** may be selectively applied to cover only the electrode surface and not the entire circumference of the distal end tubing **26**. This approach will allow the catheter device **10** to better retain its flexibility for passive or active manipulation during use, as well as reduce the "slippery" effect of the regenerated cellulose coating.

After the final curing, the distal end tubing **26**, primer coating **48** and regenerated cellulose layer **46** effectively become a single composite structure, thereby preventing the regenerated cellulose **46** from substantially moving axially, radially and/or wrinkling relative to the distal end tubing **26** during use of the catheter device **10**.

Referring to FIGS. **5** and **6**, the primer coating **48** in a second preferred distal end assembly **12***b* is applied after the electrodes **24** are constructed. In this instance, because the primer coating **48** substantially covers the electrodes **24**, the selected primer is preferably an alternate material having a significantly lower electrical resistivity—e.g., less than about 150 ohm-cm at 500 kHz—, so as to not interfere with the electrical path between the electrodes **24** and a patient's blood stream and/or body tissue during use.

The curing process for the primer coating **48** for the distal end assembly **12***b* is substantially the same as discussed above in conjunction with the distal end assembly **12***a*. Notably, however, because many ink compounds suitable for use in electrode construction are polyurethane-based, the base coating **48** may develop a covalent bond with the ink electrodes **24**, as well as with the distal end tubing **26**, during the primer curing process.

In still further alternate preferred embodiments, the primer coating **48** may be applied only at predetermined locations along the length of the distal end tubing **26**. By way of example, in a third preferred distal end assembly **12***c* illustrated in FIG. **7**, the primer **48** is only applied at respective ends **36** of the distal end assembly **12***c*. Such an arrangement allows for ease in device construction and a wider selection of primers such as, e.g., solvent-based adhesives such as cyanoacrylate or epoxy, for the primer coating **48**. In particular, employing distal end assembly **12***c* substantially eliminates the risk that the selected primer **48** may interfere with the conductivity of the regenerated cellulose **46** covering the electrodes **24**, while still providing a sufficient bond of the outer protective layer **46** to the distal end tubing **26** for certain applications.

As will be appreciated from the present disclosure, many alternate configurations employing the underlying teachings of the present invention are possible, whereby the primer or adhesive **48** is applied only to selective areas of the catheter distal end assembly **12**. By way of non-limiting example, a non-conductive primer or adhesive could be applied to the non-conductive areas of the distal end tubing **26** between the electrodes **24**.

Where an adhesive such as epoxy or cyanoacrylate is used as the primer coating **48** (e.g., applied to the "bond" points **36** in the distal end assembly **12***c*), heat is applied to the assembly **12***c* after the regenerated cellulose coating **46** is formed, in order to re-activate the cyanoacrylate and bond the regenerated cellulose layer to the distal end tubing **26**. Alternately, a solvent able to pass through the regenerated cellulose membrane, such as acetone or diluted nitromethane, could be used to re-activate the (previously cured) cyanoacrylate and form the bond between the regenerated cellulose coating **46** and distal end tubing **26**.

In accordance with a still further alternative method, the catheter device **10**, including the uncoated distal end assembly **12** including electrodes **24** and regenerated cellulose coating **46** is fully assembled without applying the primer coating **48**. An adhesive such as cyanoacrylate or epoxy in a solvent carrier having a molecular size small enough to

pass through the micro porous membrane of the regenerated cellulose is then applied over the regenerated cellulose coating **46** of the device, for example, at predetermined locations on the distal end assembly. The adhesive is then cured to drive off any solvents therein and bond the regenerated cellulose coating to the distal end tubing **26**.

Notably, the regenerated cellulose micropore size may be controlled at the time the coating **46** is formed on the distal end assembly **12**. As such, a predetermined pore size may be obtained to accommodate larger adhesive molecules, if desired. Of course, the pore size should be sufficiently small to prevent biological macromolecules, such as proteins, from passing through the regenerated cellulose structure after the bonding process is complete.

In additional alternatives, a wide variety of electrode shapes and/or sensors may be provided on a catheter device or other instrument and coated with a bonded surface coating as described herein. For example, the foregoing catheter constructions described herein may be useful in the attachment of a regenerated cellulose balloon to an anchor point on a catheter device.

Accordingly, a catheter device or other instrument made in accordance with the present invention includes a barrier that is electrically conductive, optically transparent, and/or ultrasonically transparent, yet prohibits biological macromolecules from directly or indirectly contacting the components on the instrument during use. The regenerated cellulose coating forms a closely fitting conformal sheath onto the catheter distal end assembly, that is durable and does not readily stretch substantially. Because of the protection afforded by the coating, less expensive and more efficient manufacturing procedures may be used to make the electrodes or other components on the catheter device, such as the pad printing process described above.

In addition, catheter devices are often aggressively twisted or subjected to torque during use, which may cause the coating to twist or wrinkle, potentially causing a discontinuity between the electrode and an non-bonded (i.e. mechanical interference fit) coating. Because the regenerated cellulose coating is bonded to the device, the direct contact between the coating and the underlying electrode is substantially maintained, minimizing the chance of poor, intermittent, or even lost electrical contact with the electrode. Thus, lower noise recordings, more consistent pacing thresholds, and more predictable ablation conditions may be obtained with a device manufactured in accordance with the present invention.

Thus, preferred embodiments have been disclosed of invasive medical catheters with distal end assemblies having a protective surface coating bonded thereto. While embodiments and applications of this invention have been shown and described, as would be apparent to those skilled in the art, many more modifications and applications are possible without departing from the inventive concepts herein.

The scope of the inventions, therefore, are not to be restricted except in the spirit of the appended claims.

What is claimed:

1. A catheter device, comprising:

an elongate catheter body;

a distal end electrode assembly integrally attached to the catheter body, wherein the distal end electrode assembly comprises at least one conductive electrode;

a microporous coating at least partially bonded to the distal end assembly; and

a primer coating underlying at least a portion of the microporous coating, wherein the primer coating bonds the microporous coating to the distal end assembly and wherein the primer coating covers at least a portion of one or more electrodes.

2. The catheter device of claim **1**, wherein the primer coating covers all of at least one of the electrodes thereby forming at least one coated electrode.

3. The catheter device of claim **2**, wherein the primer coating has an electrical resistivity such that the primer coating will not interfere with the electrical path between the coated electrodes and any biological material that the electrode assembly touches.

4. The catheter device of claim **1**, wherein the primer coating covers all of each of the electrodes thereby forming one or more coated electrodes.

5. The catheter device of claim **4**, wherein the primer coating has an electrical resistivity such that the primer coating will not interfere with the electrical path between the coated electrodes and any biological material that the electrode assembly touches.

6. The catheter device of claim **5**, wherein the electrical resistivity is such that the primer coating will not create an electrical short between any coated electrode and any other coated electrode.

7. The catheter device of claim **1**, wherein the microporous coating covers all of the electrodes.

8. The catheter device of claim **1**, wherein the microporous coating covers all of the distal end electrode assembly.

9. A catheter device, comprising:

an elongate catheter body;

a distal end electrode assembly integrally attached to the catheter body, wherein the distal end electrode assembly comprises a plurality of conductive electrodes;

a microporous coating at least partially bonded to the distal end assembly; and

a primer coating underlying at least a portion of the microporous coating, wherein the primer coating bonds the microporous coating to the distal end assembly, and wherein the primer coating does not completely underlie all of the microporous coating.

10. The catheter device of claim **9**, wherein the primer coating does not completely cover any of the electrodes.

11. The catheter device of claim **9**, wherein the primer coating underlies less than half of the microporous coating.

12. The catheter device of claim **11**, wherein the distal end electrode assembly further comprises a non-conductive polymer body that has a distal end and a proximal end and wherein the primer coating underlies the microporous coating at both the distal and proximal ends of the non-conductive polymer body.

13. The catheter device of claim **9**, wherein the microporous coating covers all of the electrodes.

14. The catheter device of claim **9**, wherein the microporous coating covers all of the distal end electrode assembly.

* * * * *

US006143150A

United States Patent [19]

Nagai et al.

[11] Patent Number: 6,143,150

[45] Date of Patent: Nov. 7, 2000

[54] **BIOLOGICAL GAS SENSOR**

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[73] Assignee: **Nihon Kohden Corporation**, Tokyo, Japan

[21] Appl. No.: **08/887,631**

[22] Filed: **Jul. 3, 1997**

[30] **Foreign Application Priority Data**

Jul. 3, 1996 [JP] Japan 8-173699
May 28, 1997 [JP] Japan 9-138196

[51] **Int. Cl.**[7] **G01N 27/26**

[52] **U.S. Cl.** **204/431**; 204/403; 204/415

[58] **Field of Search** 204/403, 415, 204/416, 418, 431; 205/782.5, 783, 785.5, 789; 73/23.2, 23.3, 31, 31.02; 600/311, 348, 353; 436/167, 68, 62; 422/84, 86, 88, 90

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,932,583	1/1976	Schievelbein	423/232
3,988,233	10/1976	Gamer et al.	204/415
4,141,800	2/1979	Bruer et al.	205/779.5
4,218,298	8/1980	Shimada et al.	204/195
4,460,451	7/1984	Inoue et al.	204/415
4,474,183	10/1984	Yano et al.	128/635
4,643,192	2/1987	Fiddian-Green	128/632
5,071,526	12/1991	Pletcher et al.	205/782.5
5,179,002	1/1993	Fehder	435/25
5,212,092	5/1993	Jackson et al.	436/11

FOREIGN PATENT DOCUMENTS

0 102 033	3/1984	European Pat. Off. .	
0 355 896	2/1990	European Pat. Off. .	
0 572 156	12/1993	European Pat. Off. .	
61-144562	7/1986	Japan	G01N 27/30
7-231885	9/1995	Japan	A61B 5/14

Primary Examiner—T. Tung
Assistant Examiner—Alex Noguerola
Attorney, Agent, or Firm—Sughrue, Mion, Zinn, Macpeak & Seas, PLLC

[57] **ABSTRACT**

A biological gas sensor for measuring a carbon dioxide partial pressure in an alimentary canal while excluding the influences of hydrogen sulfide and/or weak acid is disclosed. The gas sensor comprises a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution, a liquid holding part which is formed of a gas permeable tube having in the inside thereof the sensitive part of the sensor, an isotonic solution which is held in the liquid holding part and is isotonic with the bicarbonate buffer solution, and a metallic member (e.g., a coil of copper wire) so that hydrogen sulfide entering the liquid holding part may react with the metal and precipitate.

17 Claims, 9 Drawing Sheets

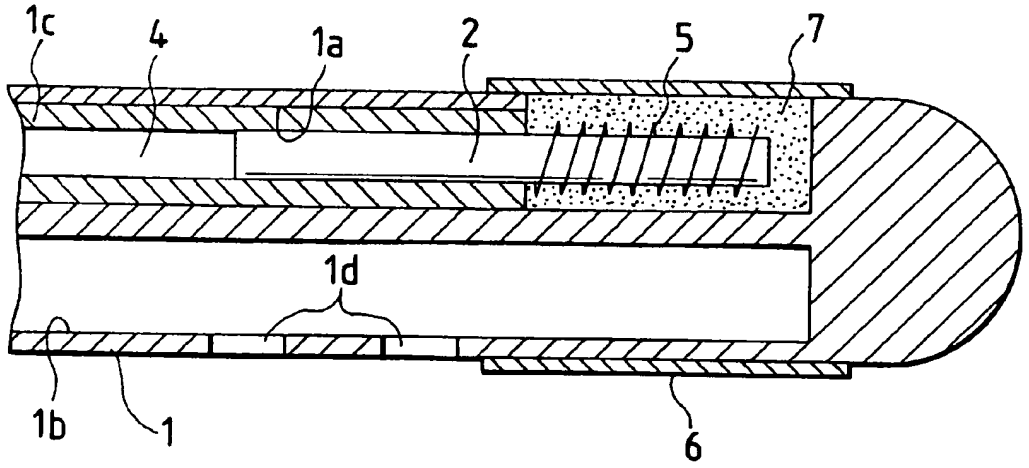


FIG. 1

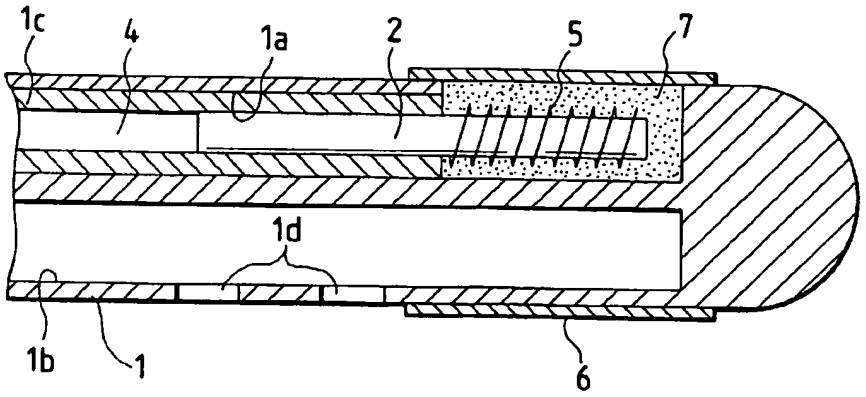


FIG. 2

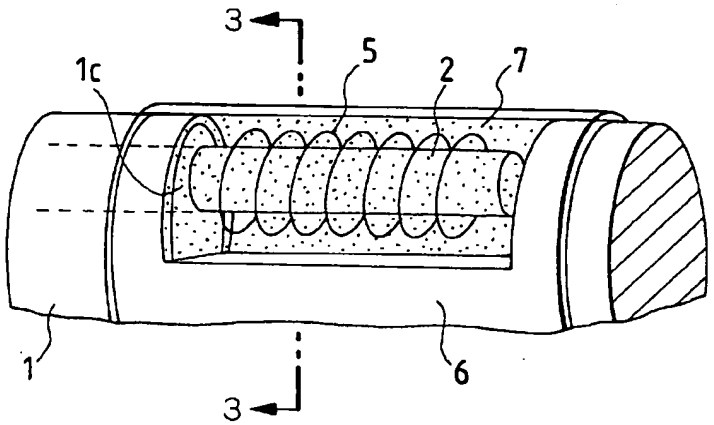


FIG. 3

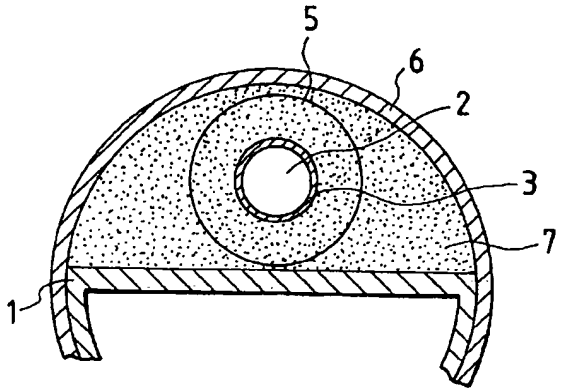


FIG. 4

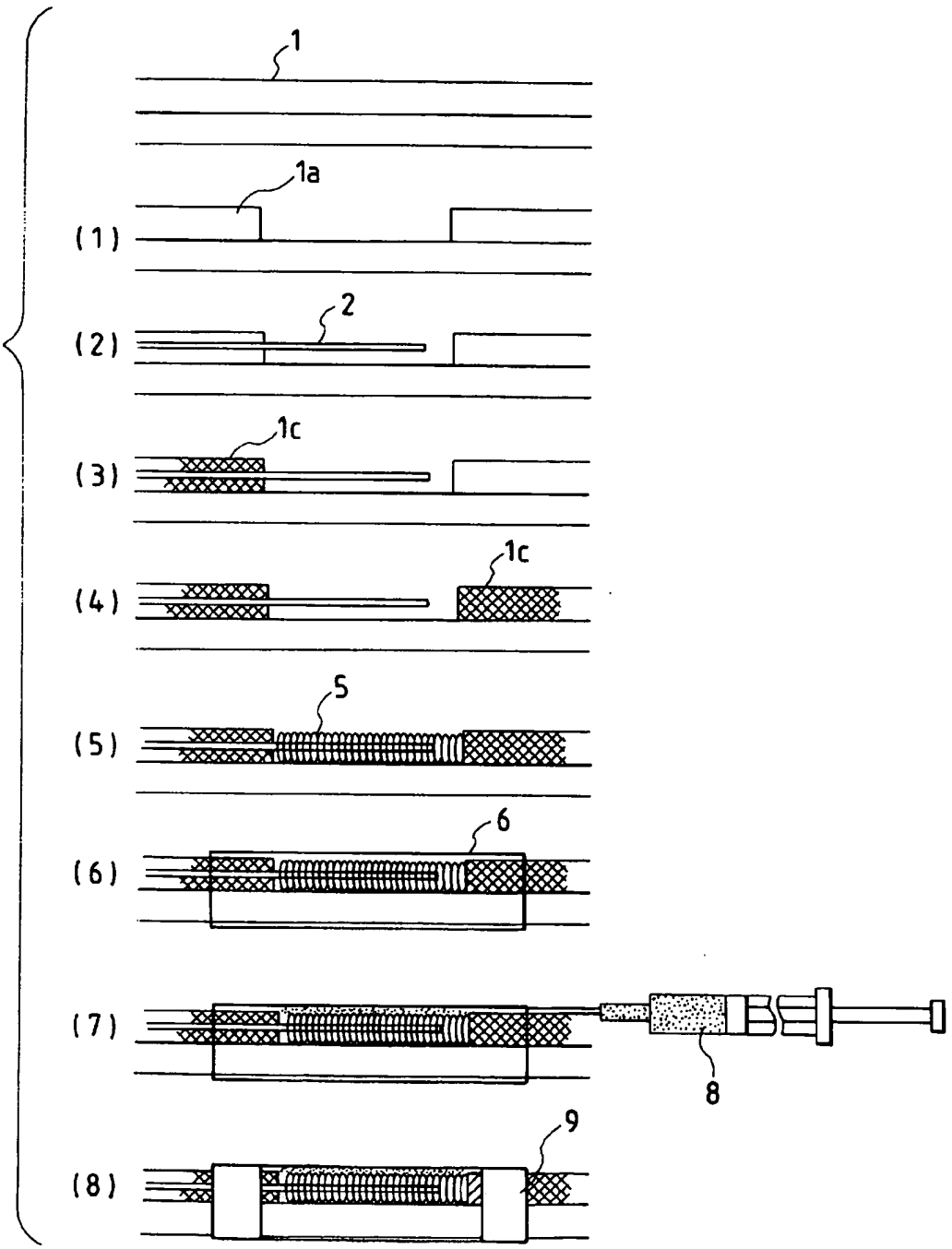


FIG. 5

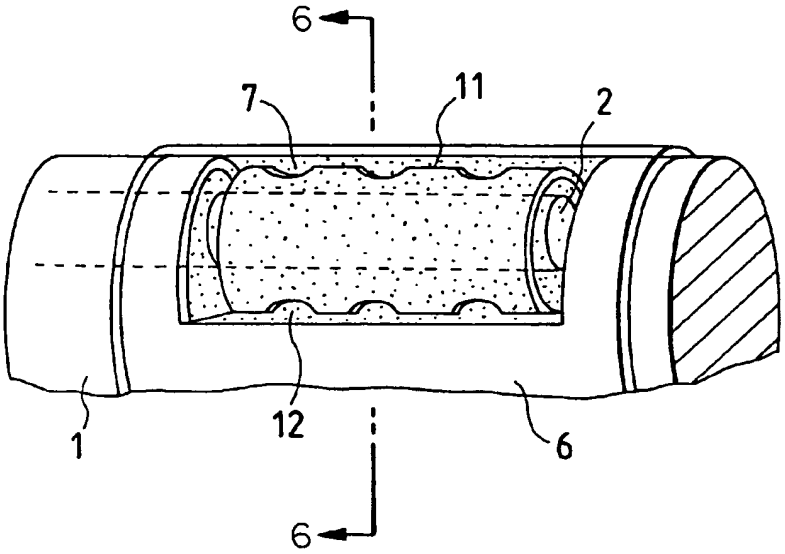


FIG. 6

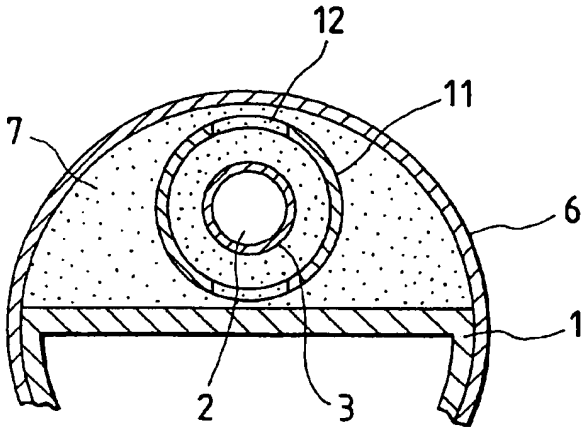


FIG. 7

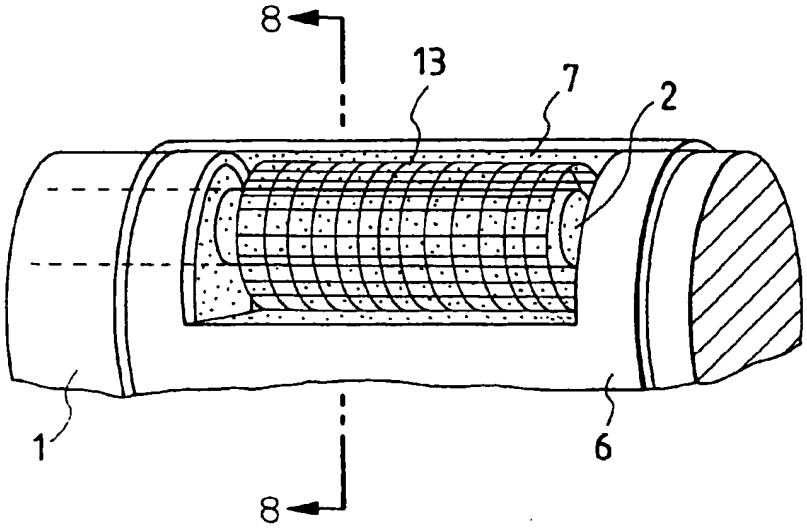


FIG. 8

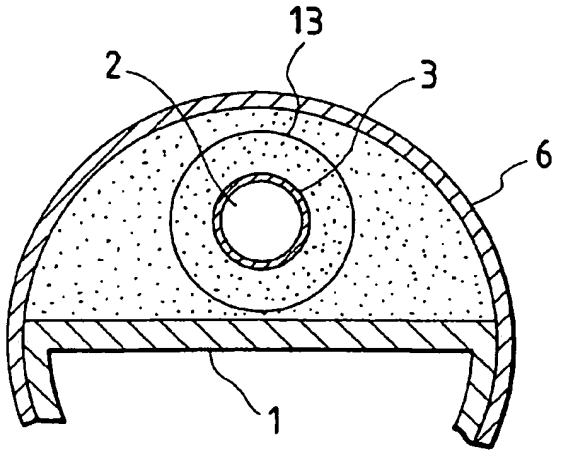


FIG. 9

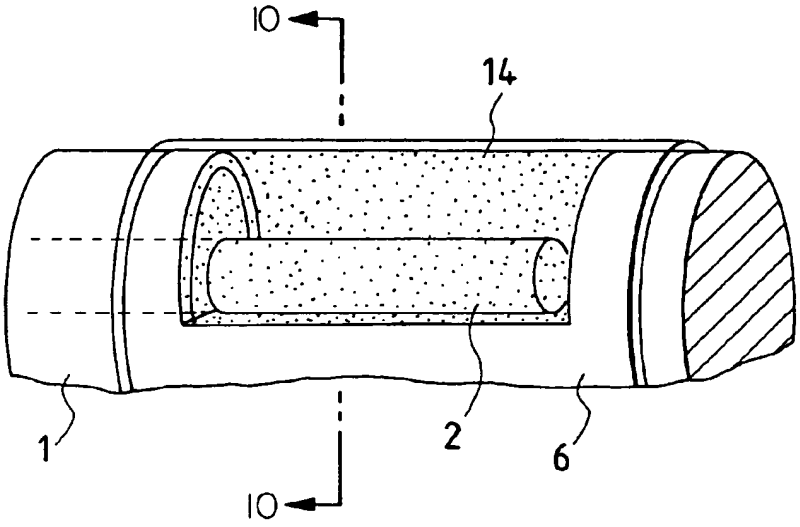


FIG. 10

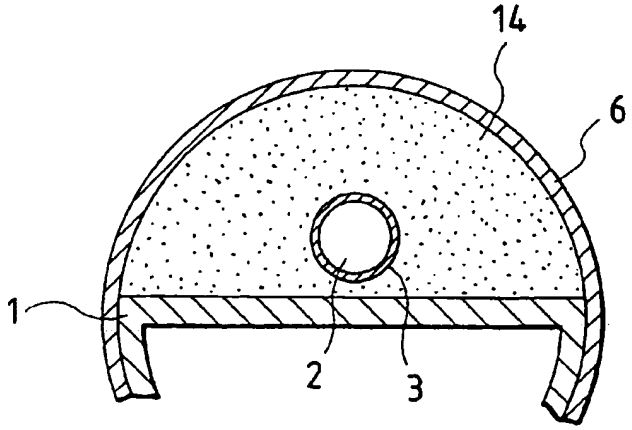


FIG. 11

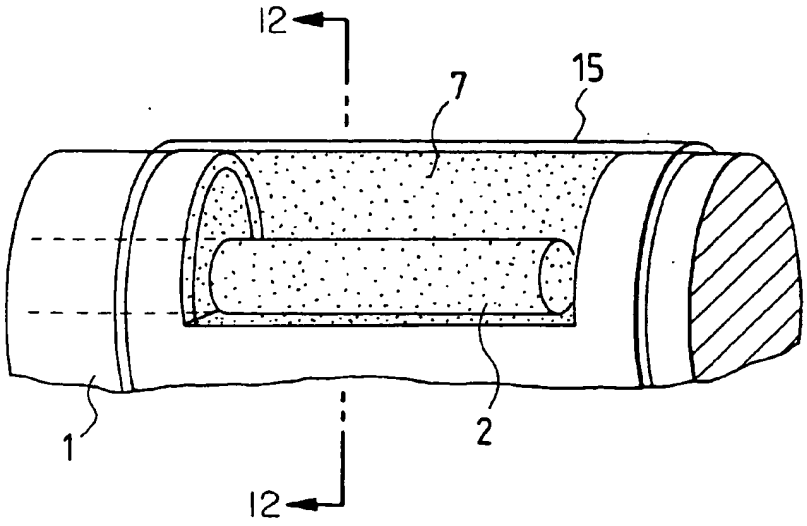


FIG. 12

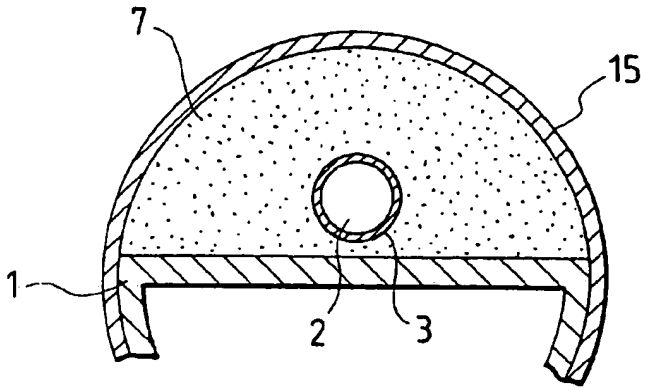


FIG. 13

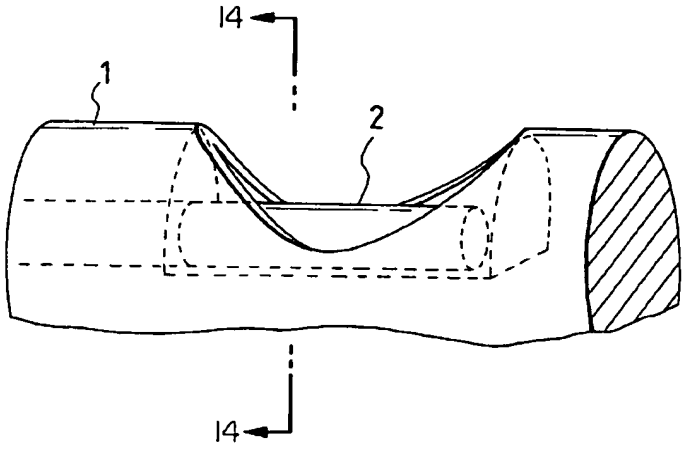


FIG. 14

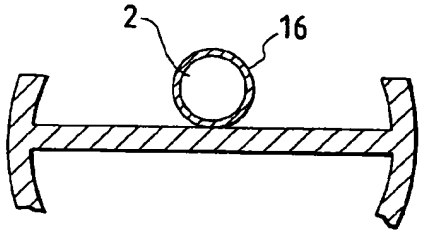


FIG. 15

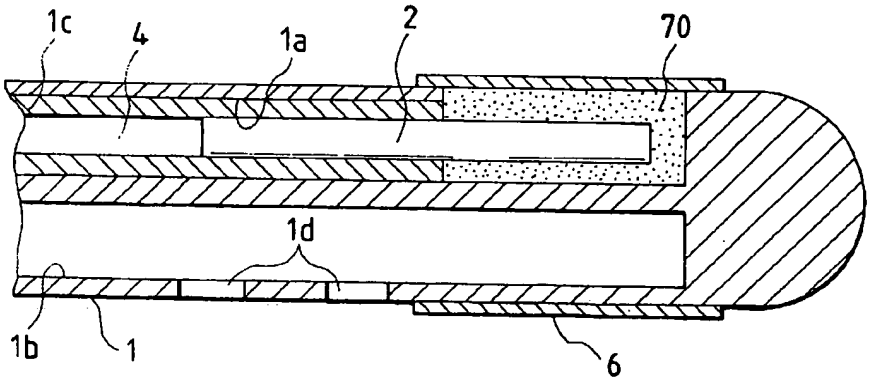


FIG. 16

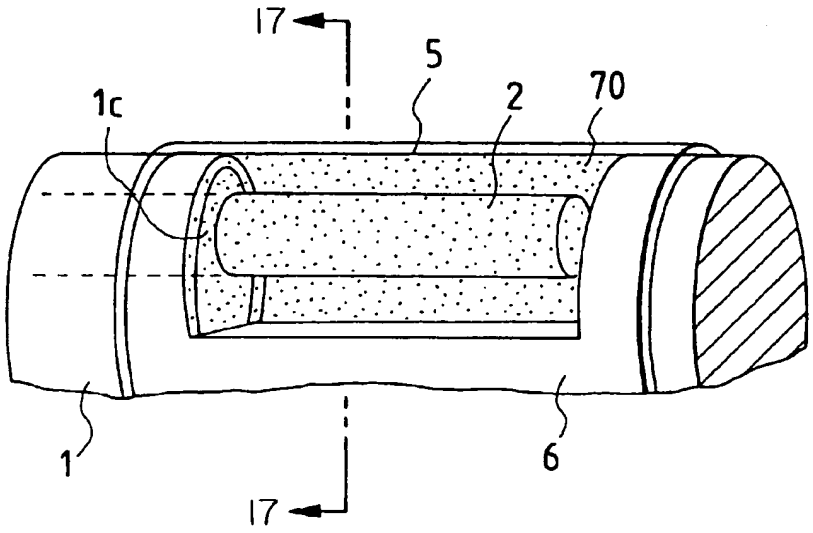


FIG. 17

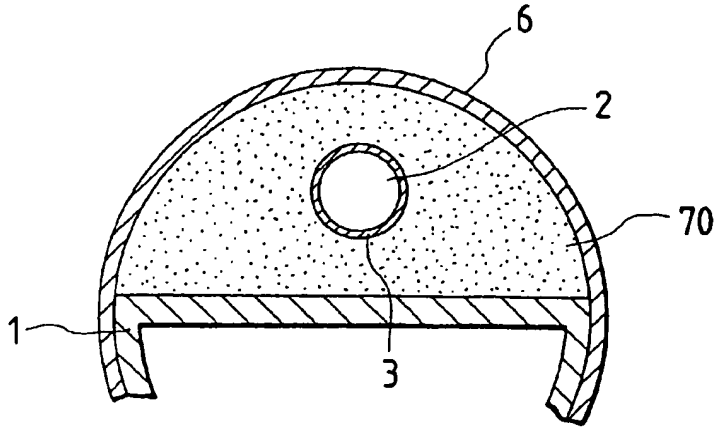


FIG. 18

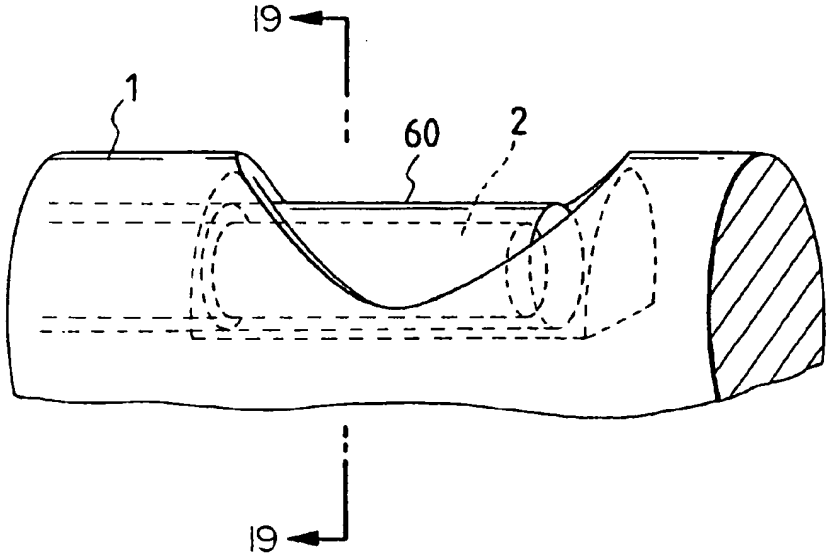
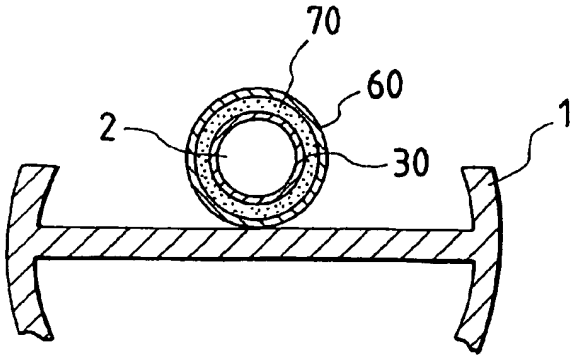


FIG. 19



BIOLOGICAL GAS SENSOR

FIELD OF THE INVENTION

This invention relates to an improved biological gas sensor for measuring a carbon dioxide partial pressure in an alimentary canal, mainly the esophagus and the gastrointestinal tube.

BACKGROUND OF THE INVENTION

In case a circulating blood flow decreases by some cause in, for example, a patient in intensive care unit (ICU), the blood that has been supplied to the organs in the abdominal cavity is redistributed to the other important organs. As a result, the blood flow in the mucous membrane of the alimentary canal begins to decrease earlier than the other organs to fall into hypoperfusion. It follows that the mucous membrane falls into hypoxemia, which leads to acidosis of the tissue. The mucous tissue is then destroyed to allow colonic bacteria or endotoxin into the body fluids, causing sepsis or multiple organ failure. That is, early finding and early treatment of hypoperfusion in the alimentary canal could remove one of the causes of multiple organ failure, which is said to be a main cause of death in ICU. In order to detect an increase in carbon dioxide partial pressure due to hypoperfusion, a sensor for a carbon dioxide partial pressure in an alimentary canal has been proposed, which is to be fitted to the tip of a stomach tube or an ileus tube inserted into the alimentary canal for medical treatment, as disclosed in JP-A-7-231885 (the term "JP-A" as used herein means an "unexamined published Japanese patent application"). The carbon dioxide gas sensor to be used includes the one described in JP-A-61-144562, which detects the concentration of carbon dioxide dissolved in a bicarbonate buffer solution (e.g., $NaHCO_3$ solution) as a change in hydrogen ion concentration by means of an Ion-Sensitive Field-Effect Transistor (ISFET).

However, the conventional biological gas sensor of this type tends to indicate a higher level than the actual carbon dioxide partial pressure, failing to make accurate measurement, because the hydrogen ion concentration of a bicarbonate buffer solution contained in the sensitive part is liable to increase in the presence of hydrogen sulfide gas or compounds thereof and/or weak acids or gas thereof which exist in the alimentary canal.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a biological gas sensor with which a carbon dioxide partial pressure in an alimentary canal can be measured accurately without being affected by the presence of hydrogen sulfide gas or compounds thereof and/or weak acids or gas thereof.

The present invention provides a biological gas sensor comprising a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution, a liquid holding part which has in the inside thereof the sensitive part of the sensor and at least a part of the inner wall thereof is made of a gas permeable membrane, an aqueous solution which is held in the liquid holding part and is substantially isotonic with the bicarbonate buffer solution, and a metallic member which is in the liquid holding part and is reactive with hydrogen sulfide.

In a preferred embodiment of the above-described gas sensor, the metallic member is a coil, a cylinder with perforations or a cylinder made of a net, through which the sensor is inserted.

The present invention also provides a biological gas sensor comprising a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution, a liquid holding part which has in the inside thereof the sensitive part of the sensor and at least a part of the inner wall thereof is made of a gas permeable membrane, and an aqueous solution which is held in the liquid holding part, is substantially isotonic with the bicarbonate buffer solution, and contains a metallic ion or a metallic compound capable of reacting with hydrogen sulfide.

The present invention further provides a biological gas sensor comprising a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution, a liquid holding part which has in the inside thereof the sensitive part of the sensor and at least a part of the inner wall thereof is made of a gas permeable membrane containing powder of a metal or a compound thereof capable of reacting with hydrogen sulfide, and an aqueous solution which is contained in the liquid holding part and is substantially isotonic with the bicarbonate buffer solution.

The present invention furthermore provides a biological gas sensor comprising a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution, wherein the gas permeable membrane contains powder of a metal or a compound thereof capable of reacting with hydrogen sulfide.

In a preferred embodiment of the above-described gas sensors, the metal is selected from the group consisting of copper, silver, cobalt, nickel, iron, manganese, and molybdenum.

The present invention furthermost provides a biological gas sensor comprising a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution, a liquid holding part which has in the inside thereof the sensitive part of the sensor and at least a part of the inner wall thereof is made of a gas permeable membrane, and an aqueous alkaline solution which is contained in the liquid holding part and is substantially isotonic with the bicarbonate buffer solution.

In a preferred embodiment of the above gas sensor, the gas sensor has a means for allowing carbon dioxide gas into the bicarbonate buffer solution in the sensitive part thereof while preventing hydrogen sulfide or compound gases thereof from reaching the bicarbonate buffer solution. This means is preferably a gas permeable membrane containing powder of a metal or a compound thereof capable of reacting with hydrogen sulfide, which is used for holding the bicarbonate buffer solution of the sensitive part.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a first embodiment of the gas sensor according to the present invention.

FIG. 2 shows a principal part of the gas sensor of FIG. 1.

FIG. 3 is a cross section along 3—3 line shown in FIG. 2.

FIG. 4 illustrates the steps of producing the gas sensor according to the first embodiment.

FIG. 5 shows a principal part of a second embodiment of the gas sensor according to the present invention.

FIG. 6 is a cross section along 6—6 line shown in FIG. 5.

FIG. 7 shows a principal part of a third embodiment of the gas sensor according to the present invention.

FIG. 8 is a cross section along 8—8 line shown in FIG. 7.

FIG. 9 shows a principal part of a fourth embodiment of the gas sensor according to the present invention.

FIG. 10 is a cross section along 10—10 line shown in FIG. 9.

FIG. 11 shows a principal part of a fifth embodiment of the gas sensor according to the present invention.

FIG. 12 is a cross section along 12—12 line shown in FIG. 11.

FIG. 13 shows a principal part of a sixth embodiment of the gas sensor according to the present invention.

FIG. 14 is a cross section along 14—14 line shown in FIG. 13.

FIG. 15 shows a seventh embodiment of the gas sensor according to the present invention.

FIG. 16 shows a principal part of the gas sensor of FIG. 15.

FIG. 17 is a cross section along 17—17 line shown in FIG. 16.

FIG. 18 shows a principal part of an eighth embodiment of the gas sensor according to the present invention.

FIG. 19 is a cross section along 19—19 line shown in FIG. 18.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows the whole structure of the first embodiment of the gas sensor according to the present invention. In FIG. 2 is shown the principal part of the gas sensor of FIG. 1, the cross section of which along 3—3 line is shown in FIG. 3.

As shown in FIGS. 1 through 3, sensor 2 is set in one of the lumens (lumen 1*a*) provided near the tip of double lumen catheter 1 made of silicone. Sensor 2 is of the type disclosed in JP-A-61-144562, being composed of ISFET, a bicarbonate buffer solution, and a gas permeable membrane. The surface of the sensitive part of sensor 2 is intimately covered with silicone-made gas permeable membrane 3 (see FIG. 3). Double lumen catheter 1 has a hemispherical shape at the tip, and the two lumens 1*a* and 1*b* each have a closed end at the side of the tip. To sensor 2 is connected one end of lead 4 (see FIG. 1) which is also inserted in lumen 1*a*, with the other end thereof connected to a measuring instrument externally provided.

Part of the wall on the side of lumen 1*a* is cut away to make an opening near the tip of catheter 1 so that the sensitive part of sensor 2 is exposed to the outer environment through the opening. The space between sensor 2 and lead 4 and the inner wall of lumen 1*a* is filled with silicone resin 1*c*. A coil of copper wire 5 is put over the sensitive part of sensor 2 with a certain gap therebetween. Gas permeable tube 6 made of silicone is fitted around the periphery of double lumen catheter 1 so as to cover the opening. Tube 6 and the outer wall of double lumen catheter 1 are tightly adhered with a silicone, and there is formed a closed space at the cut-away part of lumen 1*a* which serves as a liquid holding part. The liquid holding part, in which the sensitive part of sensor 2 is exposed, is filled with isotonic liquid 7, such as physiological saline, that is isotonic with the electrode internal liquid of sensor 2, i.e., a bicarbonate buffer solution.

The inside of lumen 1*b* is open to the outer environment through a plurality of openings 1*d* provided in a single line in the longitudinal direction in the vicinity of the tip of double lumen catheter 1. Lumen 1*b* is for discharging secreting fluid from an alimentary canal or for supplying liquid to an alimentary canal for lavage and the like.

Part of the steps for producing the biological gas sensor of the first embodiment are shown in FIG. 4. Included are a step of setting sensor 2 in silicone-made double lumen catheter 1, a step of providing copper wire 5 in a coil around sensor 2, a step of forming a liquid holding part, and a step of filling the liquid holding part with isotonic liquid 7. In more detail, these steps are carried out as follows.

(1) The wall of silicone-made double lumen catheter 1 on the side of lumen 1*a* is cut off over a length of 3 cm in the longitudinal direction and over the whole width of lumen 1*a*.

(2) Sensor 2 is inserted through lumen 1*a* so as to be positioned at the center of the cut-away portion.

(3) Silicone resin 1*c* is injected into the root of sensor 2 to fix sensor 2 in double lumen catheter 1.

(4) Silicone resin 1*c* is also injected into the other side of lumen 1*a* (the tip side) to clog lumen 1*a*.

(5) Copper wire 5 in a coil having a length of 3 cm is put over sensor 2.

(6) Silicone-made gas permeable tube 6 having a length of 5 cm whose inner diameter is equal to the outer diameter of double lumen catheter 1 is swollen with n-hexane as an organic solvent and then fitted on double lumen catheter 1 to cover the opening thereby forming a liquid holding part. On allowing tube 6 to stand, n-hexane vaporizes to achieve shrink-fit.

(7) Physiological saline is injected into the liquid holding part through between tube 6 and double lumen catheter 1 by means of syringe 8.

(8) The gap between double lumen catheter 1 and both ends of tube 6 are filled with silicone resin 9 to adhere them.

When the biological gas sensor having the above-described structure is inserted into the alimentary canal of a patient, carbon dioxide gas and hydrogen sulfide gas present in the outside fluid pass through gas permeable tube 6 and reach isotonic liquid 7, where hydrogen sulfide gas reacts with copper wire 5 and a copper ion (Cu++) dissolved therefrom as represented by reaction formula:

$$Cu^{++}+H_2S \rightarrow CuS\downarrow+2H^+$$

As a result, hydrogen sulfide gas precipitates as copper sulfide in isotonic solution 7 and cannot pass through gas permeable membrane 3 on the surface of the sensitive part of sensor 2. Thus, hydrogen sulfide gas is selectively removed, whereas only carbon dioxide gas reaches the sensitive part of sensor 2.

In order to demonstrate the mechanism of action of the gas sensor according to the present invention, an experiment was carried out as follows. Each of the gas sensor according to the first embodiment of the present invention and a conventional biological gas sensor having no copper wire was calibrated with a standard solution having a carbon dioxide partial pressure of 36 mmHg or 84 mmHg. The thus calibrated gas sensor was immersed in a 20 ppm hydrogen sulfide aqueous solution for 1 hour and then immersed in the same standard solution as used above. The values indicated by the gas sensors are shown in Table 1 below.

TABLE 1

	CO_2 Partial Pressure (mmHg)	
Standard Solution	36	84
Conventional Sensor	112	250
Sensor of the Invention	38	85

As can be seen from Table 1, the biological gas sensor of the present invention accurately detects a carbon dioxide partial pressure without being affected by hydrogen sulfide gas compared with the conventional biological gas sensor.

A second embodiment of the present invention are shown in FIGS. **5** and **6**. FIG. **5** illustrates the principal part, and FIG. **6** is a cross section along line **6—6** of FIG. **5**. The only difference of the second embodiment from the first one resides in that copper wire **5** in a coil of the first embodiment is replaced with perforated cylinder **11** made of copper. Cylinder **11** has a plurality of perforations **12** in pair (three pairs in FIG. **5**), each pair facing to each other. The other constituent elements are the same as those in the first embodiment. The action and effect produced by such a structure are equal to those obtained by the first embodiment.

FIGS. **7** and **8** illustrate a third embodiment of the present invention. FIG. **7** shows the principal part, and FIG. **8** is a cross section along line **8—8** of FIG. **7**. The difference of the third embodiment from the first one consists in that copper wire **5** in a coil of the first embodiment is replaced with cylinder **13** made of a copper net. The other constituent elements are the same as those in the first embodiment. The action and effect produced by such a structure are equal to those obtained by the first embodiment.

FIGS. **9** and **10** show a fourth embodiment of the present invention. FIG. **9** shows the principal part, and FIG. **10** is a cross section along line **10—10** of FIG. **9**. In this embodiment, copper wire **5** of the first embodiment is not used, and isotonic liquid **7** (e.g., saline) as used in the first embodiment is replaced with isotonic liquid **14** containing a copper compound. The other constituent elements are the same as those in the first embodiment. The action and effect produced by such a structure are equal to those obtained by the first embodiment.

FIGS. **11** and **12** show a fifth embodiment of the present invention. FIG. **11** shows the principal part, and FIG. **12** is a cross section along line **12—12** of FIG. **11**. In this embodiment, copper wire **5** of the first embodiment is not used, and, instead, silicone-made tube **6** as used in the first embodiment is replaced with gas permeable tube **15** made of silicone containing copper powder. The other constituent elements are the same as those in the first embodiment. According to this structure, hydrogen sulfide gas undergoes reaction with copper on the outer and inner surfaces of tube **15** and settled thereon as copper sulfide. Therefore, hydrogen sulfide cannot reach the inside isotonic liquid **7**, whereby the same action and effect as observed in the first embodiment result.

FIGS. **13** and **14** show a sixth embodiment of the present invention. FIG. **13** shows the principal part, and FIG. **14** is a cross section along line **14—14** of FIG. **13**. This embodiment does not have copper wire **5**, tube **6**, and isotonic liquid **7** used in the first embodiment, but, instead, silicone-made gas permeable membrane **3** as used in the first embodiment is replaced with gas permeable membrane **16** which is made of silicone containing copper powder. Further, while in the first embodiment the cuts made at both ends of the opening of the wall of lumen **1***a* at the side of the root of sensor **2** and the side nearer to the tip of the double lumen catheter **1** are both perpendicular to the partition between lumen **1***a* and lumen **1***b*, in the sixth embodiment the cuts are diagonal to the partition in such a manner that the area of the remaining wall covering the sensitive part of sensor **2** gradually increases from the center of the sensitive part toward the root and the tip thereof. Such a way of cutting is for protection of the sensitive part of sensor **2**. The other constituent elements are the same as those in the first embodiment. According to this structure, hydrogen sulfide gas undergoes reaction with copper on the outer and inner surfaces of gas permeable member **16** and settled thereon as copper sulfide. Therefore, hydrogen sulfide cannot reach the inside bicarbonate buffer solution whereby the same action and effect as obtained in the first embodiment result.

While in the foregoing embodiments copper is used as a metal reactive with hydrogen sulfide, other metals capable of reacting with hydrogen sulfide produce the same effect. Taking safety to the human body and ease of production into consideration, silver, cobalt, nickel, iron, manganese, and molybdenum are suitable in addition to copper. The reactions between these metals and hydrogen sulfide are represented by the following formulae:

Ag: $2Ag^{+}+H_2S \rightarrow Ag_2S\downarrow+2H^{+}$

Co: $Co^{++}+H_2S \rightarrow CoS\downarrow+2H^{+}$

Ni: $Ni^{++}+H_2S \rightarrow NiS\downarrow+2H^{+}$

Fe: $Fe^{++}+H_2S \rightarrow FeS\downarrow+2H^{+}$

$2Fe^{+++}+3H_2S\downarrow Fe_2S_3\downarrow+6H^{+}$

Mn: $Mn^{++}+H_2S \rightarrow MnS\downarrow+2H^{+}$

Mo: $Mo^{++++}+2H_2S\downarrow MoS_2\downarrow+4H^{+}$

$Mo^{++++++}+3H_2S \rightarrow MoS_3\downarrow+6H^{+}$

Of these metals, those suited to the first to third embodiments are copper, silver, nickel, iron, and molybdenum.

Metallic compounds which can be used in preparing an isotonic liquid practical for the fourth embodiment, i.e., an aqueous solution containing a metal ion include $AgClO_4$, AgF, $AgNO_3$, $CuBr_2$, $CuCl_2$, $Cu(NO_3)_2$, $CuSO_4$, CuC_2O_4, $FeBr_2$, $FeCl_2$, $FeCl_3$, $Fe(ClO_4)_2$, $Fe(ClO_4)_3$, $Fe(NO_3)_2$, $Fe(NO_3)_3$, $NiBr_2$, $NiCl_2$, $Ni(ClO_4)_2$, NiI_2, $Ni(NO_3)_2$, $NiSO_4$, $(NH_4)_2MoO_4$, $CoBr_2$, $COCl_2$, CoI_2, $Co(NO_3)_2$, $CoSO_4$, $MnBr_2$, $MnCl_2$, $Mn(NO_3)_2$, and $MnSO_4$.

Metal powder useful in the fifth and sixth embodiments in addition to copper powder includes powder of CuO, Cu_2O, Ag, Ag_2O, Co, CoO, Co_2O_3, CO_3O_4, Ni, NiO, Fe, FeO, Fe_2O_3, Mn, MnO_2, Mo, and MoO_3.

FIGS. **15** through **17** show a seventh embodiment of the present invention. FIG. **15** illustrates the whole structure of this embodiment, FIG. **16** shows the principal part thereof, and FIG. **17** is a cross section along line **17—17** of FIG. **16**. As shown in FIGS. **15** to **17**, the difference of this embodiment from the first one is that copper wire **5** is not used and isotonic liquid **7**, such as physiological saline, is replaced with an aqueous alkaline solution **70** which is isotonic with the bicarbonate buffer solution of sensor **2**. The other constituent elements are the same as those in the first embodiment.

When the biological gas sensor according to the seventh embodiment is inserted into the alimentary canal of a patient, carbon dioxide gas and weak acids or gaseous molecules thereof pass through gas permeable tube **6** and

reach aqueous alkaline solution **70**, where a weak acid (HA) ionizes as follows by the action of the aqueous alkaline solution.

$$HA \rightarrow H^+ + A^-$$

The weak acid and/or gas thereof in their molecular state HA pass through gas permeable membrane **3** on the surface of the sensitive part of sensor **2** but, on ionization in aqueous alkaline solution **70**, they cannot pass any more. For example, acetic acid, which is present in gastric juice at a concentration of several hundreds of ppm, hardly ionizes in a common aqueous solution (gastric juice) because of its weak acidicity and exists substantially in its molecular state as follows.

$$CH_3COOH(>99\%) \rightarrow CH_3COO^- + H^+(<1\%)$$

In this case, molecular acetic acid CH_3COOH passes through gas permeable membrane **3** on the surface of the sensitive part of sensor **2** to give adverse influence to sensor **2**. On the other hand, if acetic acid reacts with an aqueous alkaline solution, it ionizes almost 100% as follows and no more passes through gas permeable membrane **3**, giving no adverse influence to sensor **2**.

$$CH_3COOH(\approx 0\%) \rightarrow CH_3COO^- + H^+(\approx 100\%)$$

Like this, weak acids or gaseous molecules thereof can be removed selectively by aqueous alkaline solution **70**, and only carbon dioxide gas reaches the sensitive part of sensor **2**.

In order to demonstrate the mechanism of action of the gas sensor according to the seventh embodiment, an experiment was carried out as follows. Each of the gas sensor according to the seventh embodiment and a conventional biological gas sensor having neither a copper wire nor an aqueous alkaline solution was calibrated with a standard solution having a carbon dioxide partial pressure of 35 mmHg or 84 mmHg. The thus calibrated gas sensor was immersed in 0.2% acetic acid for 21 hours at 37° C. and then immersed in the same standard solution as used above. The values indicated by the gas sensors are shown in Table 2 below. In this case, further, 100 mM-$NaHCO_3$ aqueous solution was used as the aqueous alkaline solution for the gas sensor of the present invention.

TABLE 2

	CO_2 Partial Pressure (mmHg)	
Standard Solution	35	84
Conventional Sensor	53	130
Sensor of the Invention	33	84

It is seen from Table 2 that the biological gas sensor of the present invention accurately detects a carbon dioxide partial pressure without being affected by acetic acid compared with the conventional biological gas sensor.

The pH of the aqueous alkaline solution to be used in the gas sensor and the pKa value of a weak acid to be eliminated by the aqueous alkaline solution should satisfy relationship:

$$[pKa \text{ of weak acid}] < [pH \text{ of aqueous alkaline solution}]$$

preferably,

$$pKa+3 < pH.$$

FIGS. **18** and **19** show an eighth embodiment of the present invention. FIG. **18** illustrates the principal part of the gas sensor, and FIG. **19** is a cross section along line **19**—**19** of FIG. **18**. The difference of this embodiment from the seventh one is that gas permeable tube **6** used in the seventh embodiment is not used and, instead, gas permeable tube **60** is concentrically provided around the sensitive part of sensor **2** to make a space between gas permeable membrane **3** and gas permeable tube **60**, into which aqueous alkaline solution **70** isotonic with the bicarbonate buffer solution in sensor **2** is injected, and gas permeable membrane **3** used here is gas permeable membrane **30** made of silicone containing copper oxide. The shape of the cut made in the wall of lumen **1***a* is the same as in the sixth embodiment for protection of the sensitive part of sensor **2**. The other constituent elements are the same as those in the seventh embodiment.

When carbon dioxide to be detected is present in the alimentary canal together with weak acids or gas thereof and hydrogen sulfide gas or compounds thereof, the weak acids or gas thereof are excluded by aqueous alkaline solution **70** through the same mechanism as in the seventh embodiment, and hydrogen sulfide gas or its compounds can be eliminated by gas permeable membrane **30** through the same mechanism as in the sixth embodiment. In other words, the gas sensor according to this embodiment combines the function of removing weak acids or gas thereof and the function of removing hydrogen sulfide gas or compounds thereof.

All the above-mentioned embodiments use a double lumen catheter as a means in which the gas sensor is set. This is advantageous in that carbon dioxide measurement with the gas sensor and discharge of secreting fluid from the alimentary canal or lavage of the alimentary canal can be effected simultaneously.

While ISFET is used as a sensor in the foregoing embodiments, similar action and effect can be obtained by using other sensitive systems for detecting a carbon dioxide partial pressure from changes of hydrogen ion concentration in a bicarbonate buffer solution, such as a Severinghause type electrode using a glass electrode and an optical fiber electrode coated with $NaHCO_3$ and a pH indicator dye as disclosed in JP-A-3-85430.

While silicone is used as a material of the double lumen catheter in the foregoing embodiments, other materials used in commercially available general catheters, such as polyvinyl chloride, can be used as well.

As described above, the present invention makes it possible to accurately measure a carbon dioxide partial pressure in an alimentary canal while excluding the influences of hydrogen sulfide gas or compounds thereof and/or weak acids or gas thereof that may coexist in the alimentary canal.

While the invention has been described in detail and with reference to specific examples thereof, it will be apparent to one skilled in the art that various changes and modifications can be made therein without departing from the spirit and scope thereof.

What is claimed is:

1. A biological gas sensor comprising:

a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a first gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution;

a liquid holding part which has in the inside thereof the sensitive part of said sensor and at least a part of the inner wall of said holding part is made of a second gas permeable membrane;

an aqueous solution which is held in said liquid holding part and is substantially isotonic with said bicarbonate buffer solution; and

a metallic member which is in said liquid holding part and is reactive with hydrogen sulfide.

2. A biological gas sensor according to claim 1, wherein said metallic member is a coil through which said sensor is inserted.

3. A biological gas sensor according to claim 2, wherein said metal is selected from the group consisting of copper, silver, cobalt, nickel, iron, manganese, and molybdenum.

4. A biological gas sensor according to claim 1, wherein said metallic member is a perforated cylinder through which said sensor is inserted.

5. A biological gas sensor according to claim 4, wherein said metal is selected from the group consisting of copper, silver, cobalt, nickel, iron, manganese, and molybdenum.

6. A biological gas sensor according to claim 1, wherein said metallic member is a cylinder made of a net through which said sensor is inserted.

7. A biological gas sensor according to claim 6, wherein said metal is selected from the group consisting of copper, silver, cobalt, nickel, iron, manganese, and molybdenum.

8. A biological gas sensor according to claim 1, wherein said metal is selected from the group consisting of copper, silver, cobalt, nickel, iron, manganese, and molybdenum.

9. A biological gas sensor comprising:

a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a first gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution;

a liquid holding part which has in the inside thereof the sensitive part of said sensor and at least a part of the inner wall of said holding part is made of a second gas permeable membrane; and

an aqueous solution which is held in said liquid holding part, is substantially isotonic with said bicarbonate buffer solution, and contains a metallic ion or a metallic compound capable of reacting with hydrogen sulfide.

10. A biological gas sensor according to claim 9, wherein said metal is selected from the group consisting of copper, silver, cobalt, nickel, iron, manganese, and molybdenum.

11. A biological gas sensor comprising:

a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a first gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution;

a liquid holding part which has in the inside thereof the sensitive part of said sensor and at least a part of the inner wall of said holding part is made of a second gas permeable membrane containing powder of a metal or a compound thereof capable of reacting with hydrogen sulfide; and

an aqueous solution which is contained in said liquid holding part and is substantially isotonic with said bicarbonate buffer solution.

12. A biological gas sensor according to claim 11, wherein said metal is selected from the group consisting of copper, silver, cobalt, nickel, iron, manganese, and molybdenum.

13. A biological gas sensor comprising:

a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a first gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution, wherein said gas permeable membrane contains powder of a metal or a compound thereof capable of reacting with hydrogen sulfide.

14. A biological gas sensor according to claim 13, wherein said metal is selected from the group consisting of copper, silver, cobalt, nickel, iron, manganese, and molybdenum.

15. A biological gas sensor comprising:

a sensor which has in the sensitive part thereof a bicarbonate buffer solution held by a first gas permeable membrane and detects a carbon dioxide partial pressure based on the hydrogen ion concentration of the bicarbonate buffer solution;

a liquid holding part which has in the inside thereof the sensitive part of said sensor and at least a part of the inner wall of said holding part is made of a second gas permeable membrane; and

an aqueous alkaline solution which is contained in said liquid holding part and is substantially isotonic with said bicarbonate buffer solution.

16. A biological gas sensor according to claim 15, wherein said gas sensor has a means for allowing carbon dioxide gas into the bicarbonate buffer solution in the sensitive part thereof while preventing hydrogen sulfide or compound gases thereof from reaching the bicarbonate buffer solution.

17. A biological gas sensor according to claim 16, wherein said means is said gas permeable membrane of the sensitive part which contains powder of a metal or a compound thereof capable of reacting with hydrogen sulfide.

* * * * *

United States Patent [19]

Vogel et al.

[11] **Patent Number: 4,957,110**

[45] **Date of Patent: Sep. 18, 1990**

[54] **STEERABLE GUIDEWIRE HAVING ELECTRODES FOR MEASURING VESSEL CROSS-SECTION AND BLOOD FLOW**

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[73] Assignee: **C. R. Bard, Inc.**, Murray Hill, N.J.

[21] Appl. No.: **325,223**

[22] Filed: **Mar. 17, 1989**

[51] **Int. Cl.**[5] **A61B 5/04**; A61B 5/026

[52] **U.S. Cl.** **128/642**; 128/692; 128/693; 128/772

[58] **Field of Search** 128/642, 692, 693, 772, 128/784, 786

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,730,171	5/1973	Namon	128/2.05 Z
3,742,936	7/1973	Blanie et al.	128/2.1 Z
3,773,037	11/1973	Kolin	128/2.05 F
3,882,851	5/1975	Sigworth	128/2.1 Z
3,896,373	7/1975	Zelby	324/57 R
4,176,662	12/1979	Frazer	128/6
4,236,525	12/1980	Sluetz et al.	128/786 X
4,380,237	4/1983	Newbower	128/693
4,401,127	8/1983	Littleford	128/786
4,481,953	11/1984	Gold et al.	128/786
4,545,390	10/1985	Leary	128/772
4,552,127	11/1985	Schiff	128/1 D
4,559,951	12/1985	Dahl et al.	128/642
4,587,975	5/1986	Salo et al.	128/693
4,643,202	2/1987	Roche	128/786
4,660,571	4/1987	Hess et al.	128/784
4,674,518	6/1987	Salo	128/695
4,677,990	7/1987	Neubauer	128/786
4,699,157	10/1987	Shonk	128/786
4,729,384	3/1988	Bazenet	128/691

FOREIGN PATENT DOCUMENTS

3120012	2/1983	Fed. Rep. of Germany	128/772
411842	9/1974	U.S.S.R.	128/693

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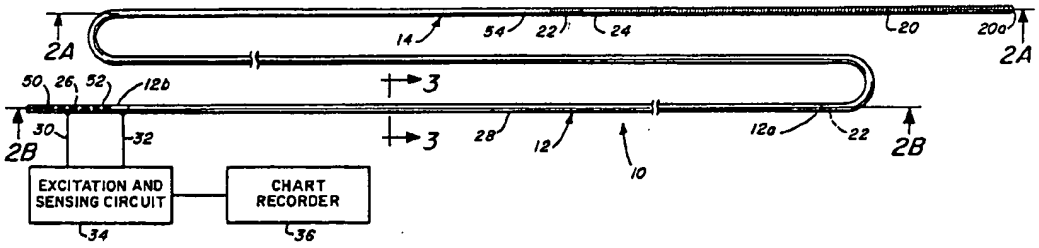
[57] **ABSTRACT**

A small diameter steerable guidewire that is used to guide a catheter in transluminal coronary angioplasty is provided with a pair of electrodes for measuring the cross-sectional area of a blood vessel and for measuring blood flow. The guidewire includes a shaft and a tip attached to the distal end of the shaft. The shaft is torsionally rigid along its length and includes a conductive tube and a wire extending through the tube. The tip, which can be bent to a prescribed curve when relaxed, is sufficiently flexible to adapt to and follow the contours of a blood vessel. The tip includes a tapered extension of the wire in the shaft. A proximal electrode and a distal electrode are coaxially mounted on the tapered wire and are electrically connected to the tube and the wire, respectively. The electrodes are axially spaced apart by a predetermined distance. Each electrode is preferably a conductive, helically-wound spring. The outside diameter of the steerable guidewire preferably does not exceed about 0.020-inch for coronary use.

40 Claims, 2 Drawing Sheets



end of guidewire 10. Wire 26 and tube 28 are connected by leads 30 and 32, respectively, to an external excitation and sensing circuit 34. The excitation and sensing circuit 34 is connected to a chart recorder 36.

Conductive tube 28 is preferably a stainless steel tube, and wire 26 is an insulated core wire of stainless steel. In a preferred embodiment, tube 28 has a outside diameter of 0.016 inch and an inside diameter of 0.010-inch. The wire 26, which typically has a diameter of 0.008-inch, is electrically insulated from tube 28 by an insulating layer 40. The insulating layer 40, which is preferably a polyimide, can be a coating on wire 26 or can be a thin tube between wire 26 and tube 28.

Wire 26 includes a tapered distal portion 26*a* which extends beyond shaft 12 into the distal tip region 14. The proximal electrode 22 comprises a helically-wound, conductive spring coaxially mounted on the tapered portion 26*a* of wire 26. In the embodiment illustrated in FIGS. 2A and 2B, proximal spring 22 extends from the distal end 12*a* of shaft 12 to spacer 24. The proximal end of spring 22 abuts against and is electrically connected to the distal end of tube 28. The spring 22 can be silver-stainless steel having an outside coil diameter of 0.016-inch. The insulating member 24 is preferably a cylindrically-shaped spacer that is coaxially mounted on tapered portion 26*a* of wire 26 and abuts against the distal end of spring 22. The spacer 24, which typically has an axial length of two millimeters, establishes the spacing between electrodes 20 and 22. The axial length of spacer 24 should be small in order to obtain a localized measurement of cross-sectional area rather than an average value over an extended length.

The distal electrode 20 is a helically-wound, conductive spring that is coaxially mounted on tapered distal portion 26*a* and abuts against spacer 24. In a preferred embodiment, spring 20 is fabricated of platinum and has an axial length of 2.5 centimeters and an outside coil diameter of 0.016-inch. The distal spring 20 is electrically connected to wire 26, preferably by soldering or brazing, at a point about seven millimeters in a distal direction from spacer 24. The tapered portion 26*a* of wire 26 terminates within distal spring 20 at a point about 1.2 centimeters from spacer 24. A rounded bead 20*a* is formed at the distal end of spring 20, and a safety wire 42 is connected between bead 20*a* and tapered portion 26*a* . Insulating layer 40 covers the tapered portion 26*a* of wire 26 such that proximal electrode 22 is electrically insulated from wire 26 in the distal tip region.

In operation, an AC signal is applied to the electrodes 20 and 22 from circuit 34. A current flows through the blood between the spaced-apart electrodes 20 and 22. The current flow is related to the cross-sectional area of the blood vessel, as described more fully in the aforementioned Pat. No. 3,896,373.

In order to improve the sensitivity of the measurement, it is desirable to provide low electrical resistance through the guidewire to opposite sides of the spacer 24. The resistances of helical springs 20 and 22 are the major contributors to the total circuit resistance. Since proximal spring 22 is typically substantially longer than distal spring 20, the resistance of proximal spring 22 would be higher than the resistance of distal spring 20 if the same materials were used. In order to approximately equalize the resistances, different spring materials can be utilized. When the distal spring 20 is platinum and the proximal spring 22 is silver-stainless steel, the resistance of each electrodes is maintained below 200 ohms. A further advantage of the configuration where the distal electrode is platinum and the proximal electrode is silver-stainless steel is that the platinum electrode is radiopaque whereas the silver-stainless steel electrode is non-radiopaque. As a result, the measurement location at spacer 24 can clearly be identified by the physician using fluoroscopic techniques. If both electrodes were radiopaque, it would be more difficult to determine the exact location of spacer 24. It will be understood that different electrode materials can be utilized depending on the resistance requirements and the requirements for radiopaque electrodes. In cases where electrode resistance is not critical, platinum is preferably utilized for both electrodes because platinum has a lesser tendency to become oxidized or corroded than other metals.

The proximal end of wire 26 extends from tube 28 into a stainless steel tube 50. Tube 50 is spaced from tube 12 by an insulating spacer 52. Wire 26 is electrically connected to tube 50. Tube 50 and spacer 52 have the same diameter as the remainder of the guidewire to facilitate sliding a catheter over guidewire 10. Tube 50 remains external to the patient during use of the guidewire 10.

As described hereinabove, tubes 28 and 50 and helical springs 20 and 22 are all made of conductive material. In order to minimize leakage currents which would affect the accuracy of measurements made with the electrodes 20 and 22, it is desirable to provide an insulating layer 54 over the portions of these elements that are not used for making measurements. The entire length of the guidewire 10, except for exposed portions of electrodes 20 and 22 on either side of spacer 24, can be covered with insulating layer. Alternatively, since the distal electrode 20 is short in comparison with the remainder of the guidewire, the insulating layer can be omitted on distal electrode 20. Preferably, about two millimeters of each electrode 20, 22 is exposed adjacent to spacer 24. The insulating layer 54 can be formed as a coating on the outer surface of guidewire 10 or as a thin tube. A preferred material is polyimide. Preferably, the total outside diameter of the guidewire, including insulating layer 54, does not exceed about 0.020-inch. The guidewire shown in FIGS. 1-3 and described hereinabove can be fabricated in accordance with the following steps:

1. Barrel and taper grind a 0.008-inch × 70-inch stainless steel core wire 26.
2. Ultrasonically clean and oxidize (by plasma etch or baking) core wire 26.
3. Draw the core wire 26 through a dimethyl formamide/amide imide solution (Four parts to one respectively) at a rate of 24-inches per minute to form an insulating coating on core wire 26.
4. Cure the coated wire 26 in an oven for one hour at 300° C.
5. Insert the coated core wire 26 into a stainless steel tube 28 having an outside diameter of 0.016-inch and an inside diameter of 0.010-inch with 31 centimeters of the tapered portion of the core wire 26 outside of tube 28.
6. Bond insulated wire 26 to tube 28 with silver-filled epoxy or other cement.
7. Place proximal spring 22 over the core wire 26 and butt against tube 28. Then bond the spring 22 to the insulated core wire 26 and to tube 28 with silver-filled epoxy or solder.
8. Cure the epoxy in an oven for one hour at 150° C.

9. Place a two millimeter spacer (0.005-inch inside diameter by 0.016-inch outside diameter) over the end of the core wire and butt against proximal spring **22**. Place distal spring **20** over the tapered core wire **26***a* and butt against spacer **24**. Bond the ends of springs **20** and **22** to the core wire **26** and to spacer **24**.
10. Push a six centimeter piece of stainless steel safety ribbon (0.001-inch×0.003-inch) into spring **20** until it stops.
11. Braze spring **20** to the safety ribbon **42** and core wire **26** at a point seven millimeters from the proximal end of spring **20**.
12. Tip weld the distal end of spring **20**.
13. Scrape off coating on core wire **26** at a point five millimeters from the proximal end of tube **28**.
14. Slide a 5 millimeter long insulating spacer **52** (0.016-inch outside diameter×0.010-inch inside diameter) over the proximal end of core wire **26** and butt against the proximal end of tube **28**.
15. Slide a 5 centimeter long tube **50** (0.016-inch outside diameter×0.010 inch inside diameter) over the proximal end of core wire **26** and butt against spacer **52**.
16. Solder tube **50** to core wire **26** at the point where the coating was scraped off.

Another preferred embodiment of the steerable guidewire is shown in FIG. **4**. The shaft portion of the guidewire is the same as the shaft of the guidewire shown in FIGS. **114 3** and described hereinabove. The shaft includes conductive tube **28** and wire **26** extending through tube **28**. Tube **28** and wire **26** are insulated from each other. A distal tip region **70** includes a tapered distal portion **26***a* of wire **26**. A proximal electrode **72** comprising a helically-wound, conductive spring is coaxially mounted on tapered distal portion **26***a*. The distal end of electrode **72** is spaced from the distal end of tube **28** by a distance on the order of **29** centimeters. Spacer **24** is coaxially mounted on tapered portion **26***a* of wire **26** abutting against proximal electrode **72**, and distal electrode **20** is mounted on tapered portion **26***a* abutting against spacer **24**. Distal electrode **20** is preferably a helically-wound platinum spring as described hereinabove. Since proximal electrode **72** is relatively short, it has approximately the same resistance as distal electrode **20** and is preferably platinum.

The proximal electrode **72** is electrically connected to tube **28** by a conductive ribbon **74**. In a preferred embodiment, the conductive ribbon **74** is a platinum wire having dimensions of 0.001 inch×0.005-inch. The ribbon **74** is soldered or brazed to tube **28** at one end and to proximal electrode **72** at the other end. An insulating tube **76** surrounds a portion of the guidewire between the distal end of tube **28** and electrode **72**. Preferably, tube **76** is fabricated of polyimide and extends from a point about two millimeters in a proximal direction from spacer **24** (thus exposing about two millimeters of electrode **72**) to the proximal end of tube **28**. The proximal electrode **72**, by way of example, can have a length of about 10 millimeters. In the embodiment of FIG. **4**, the overall length of the guidewire spring is relatively short.

In an alternative embodiment, the insulating tube **76** has a conductive coating or lining on its inside surface for electrically connecting tube **28** to proximal electrode **72**. In this embodiment, ribbon **74** can be omitted.

A schematic diagram of the excitation and sensing circuit **34** is shown in FIG. **5**. The output of a signal generator **80** is coupled through an amplitude adjustment circuit **82**, **84** to leads **30** and **32**. Leads **30** and **32** connect to wire **26** and tube **28**, respectively, of the steerable guidewire **10** as shown in FIG. **1**. Preferably, leads **30** and **32** are connected to tubes **50** and **28**, respectively, by removable clips (not shown). Signal generator **80** is preferably a sinewave generator having a frequency of 50 KHz, an output amplitude of 0.25 volts peak-to-peak and a current of 10 microamps. The AC signal is applied between electrodes **20** and **22** of the guidewire causing electrical current to flow through the blood in the region of the vessel surrounding the spacer **24**. The current flow varies with vessel cross-section adjacent to spacer **24**. The voltage between leads **30** and **32** is sensed by an amplifier comprising transistors **86** and **88** and associated components. The amplifier is powered by a battery **90**. The output of the amplifier is supplied through a transformer **91**, a rectifier **92** and a low pass filter **94** to provide an output **96** to chart recorder **36**. The output **96** is a DC voltage representative of the current flow between electrodes **20** and **22**. The output **96** can be calibrated to provide readings of the cross-sectional area of the blood vessel. It will be understood that the circuit shown in FIG. **5** is given by way of example and is not in any way limiting.

The procedure for using the guidewire in accordance with the present invention involves placement and location of a conventional guide catheter so that its distal end is adjacent to the entry to the coronary artery. A dilatation catheter is prepared with the guidewire in place as described in the aforementioned Pat. No. 4,545,390. The guidewire extends through the main lumen of the dilatation catheter so that at about two centimeters of the distal tip of the guidewire project beyond the outlet of the dilatation catheter.

The assembly of dilatation catheter and guidewire is then pushed through the guide catheter into the coronary artery with the guidewire being used to manipulate dilatation catheter selectively into deeper and smaller coronary arteries. The simultaneous advancement of the dilatation catheter and guidewire is performed with the distal portion of the guidewire projecting distally beyond the outlet of the dilatation catheter. The projecting end of the guidewire tends to bias toward the curved configuration which the surgeon has preset. As the stenosis or obstruction is approached, the guidewire is advanced independently of the dilatation catheter in order to locate the guidewire with a high degree of precision with respect to the stenosis. The guidewire is advanced to the stenosed region by a combination of pushing and rotation or steering of its proximal end. The location of the guidewire can be verified fluoroscopically because of the highly radiopague characteristic of the distal spring **20**.

When the electrodes **20** and **22** have been positioned in the stenosed region, a measurement of vessel cross-section is taken as described hereinabove. Then, the dilatation catheter is advanced over the guidewire until the balloon is located within the obstruction. The balloon is inflated to dilatate the stenosis and expand the vascular lumen. Balloon dilatation techniques are well known to those skilled in the art. After the dilatation procedure has been completed, the balloon catheter is withdrawn, at least partially, and the electrodes **20** and **22** are again positioned in the stenosed region. A second measurement of vessel cross-section is taken, thereby enabling verification of the effectiveness of the dilatation procedure. Thus, dilatation and measurement of very small vessels can be performed without removal of the balloon catheter and without insertion of a separate

measuring device. The steerable guidewire of the present invention can be used in a manner similar to that described above with a laser catheter, a hot tip device or any other transluminal angioplasty device.

In accordance with another aspect of the procedure, the guidewire having electrodes **20** and **22** can be used for measuring blood flow through the stenosed region before and after the dilatation procedure. Blood flow is measured as follows. The guidewire is advanced to the stenosed region as described above and is positioned so that electrodes **20** and **22** pass through the stenosed region to the downstream side thereof. The dilatation catheter is advanced to the upstream side of the stenosed region, and a glucose solution is injected through the lumen of the dilatation catheter. Typically, about five milliliters of glucose solution is injected over a five second period. Initially, the electrodes sense the cross sectional area of the vessel by conduction through blood. When the glucose solution is injected into the vessel, it passes through the stenosed region to the electrodes, causing a reduction in current flow between electrodes. Depending on the extent to which blood is flowing in the vessel, higher or lower concentrations of glucose solution reach the electrodes. Thus, the drop in current between electrodes **20** and **22** as the glucose solution is injected is a measure of the blood flow in the vessel.

The change in current appears as a variation or curve on the chart recorder **36** or other recording device. After the glucose solution dissipates, the measured current between electrodes **20** and **22** returns to its original value. Blood flow is determined as a function of the area under the chart recorder curve during glucose flow in accordance with the Stewart-Hamilton equation:

$$Q = \frac{kI}{A}$$

where

Q=Rate of blood flow,

A=Area under curve in ohm-sec,

I=Volume of injected glucose solution, and

k=Constant in ohms.

A flow measurement can be obtained before and after the balloon dilatation procedure to provide an indication of the effectiveness of the dilatation procedure. It will be understood that the above-described method can also be used to measure blood flow in a vessel that is not stenosed.

While there have been shown and described what are at present considered the preferred embodiments of the present invention, it will be obvious to those skilled in the art that various changes and modifications may be made therein without departing from the scope of the invention as defined by the appended claims.

What is claimed is:

1. A steerable guidewire comprising:

an elongated shaft having a distal end and a proximal end, said shaft being sufficiently torsionally rigid along its length for controllably transmitting to the distal end substantially all of the rotation applied to the proximal end, said shaft including a first electrical conductor and a second electrical conductor insulated from said first electrical conductor, said electrical conductors extending from the distal end to the proximal end of said shaft; and

a tip attached to the distal end of said shaft, said tip adapted to be bent to a desired curve, said tip being sufficiently flexible so as to adapt to and follow the contours of a blood vessel, said tip including a distal electrode electrically connected to one of said conductors and a proximal electrode electrically connected to the other of said conductors, said electrodes being axially spaced apart on said tip by a predetermined distance, said distal electrode comprising a distal, conductive, helically-wound spring and said proximal electrode comprising a proximal, conductive helically-wound spring, said tip including a tapered distal region of said second conductor passing through said proximal spring at and least a portion of said distal spring and electrically connected to said distal spring.

2. A steerable guidewire as defined in claim **1** wherein said shaft and said tip have a diameter that does not exceed about 0.020-inch.

3. A steerable guidewire as defined in claim **1** wherein said first conductor comprises a main conductive tube having a lumen therethrough.

4. A steerable guidewire as defined in claim **3** wherein said second conductor comprises a wire extending through the lumen in said tube.

5. A steerable guidewire as defined in claim **1** wherein said tube includes a distal end and wherein said tapered distal region of said second conductor includes a tapered distal region of said wire extending beyond the distal end of said tube, said tapered distal region of said wire passing through said proximal spring and at least a portion of said distal spring.

6. A steerable guidewire as defined in claim **5** wherein a distal spring is electrically connected to the tapered distal region of said wire.

7. A steerable guidewire as defined in claim **6** wherein said proximal spring is electrically connected to said tube.

8. A steerable guidewire as defined in claim **7** wherein said proximal spring and said distal spring are axially spaced apart by a cylindrical insulating spacer on said wire.

9. A steerable guidewire as defined in claim **7** wherein said proximal spring, said distal spring and said spacer have approximately equal outside diameters.

10. A steerable guidewire as defined in claim **8** further including an insulating layer around said tube and said proximal electrode except for a portion of said proximal electrode adjacent to said spacer.

11. A steerable guidewire as defined in claim **10** wherein said insulating layer comprises a polyimide sleeve.

12. A steerable guidewire as defined in claim **8** wherein said spacer has an axial length of about 2 millimeters.

13. A steerable guidewire as defined in claim **6** wherein said proximal spring is spaced from the distal end of said tube and is electrically connected thereto by a conductive ribbon.

14. A steerable guidewire as defined in claim **4** wherein said wire is insulated from said tube by an insulating coating on said wire.

15. A steerable guidewire as defined in claim **4** wherein said wire is insulated from said tube by a polyimide sleeve on said wire.

16. A steerable guidewire as defined in claim **4** further including a proximal conductive tube proximally spaced from said main tube and electrically connected to said wire.

17. A steerable guidewire as defined in claim 4 wherein said tube as an outside diameter of about 0.016-inch, and said wire has an outside diameter of about 0.008-inch.

18. A steerable guidewire as defined in claim 1 wherein said distal electrode is radiopaque.

19. A steerable guidewire as defined in claim 1 wherein said electrodes are axially spaced apart by a distance that is sufficiently small to provide highly localized measurements.

20. A small diameter steerable guidewire comprising;

a main conductive tube having a proximal end and a distal end;

a conductive wire extending through said tube and having a tapered distal region extending beyond the distal end of said tube, said wire being electrically insulated from said tube;

a distal, conductive, helically-wound spring receiving at least a portion of the distal region of said wire, said distal spring constituting a distal electrode and being electrically connected to said wire;

a proximal, conductive, helically-wound spring having the distal region of said wire extending therethrough, said proximal spring constituting a proximal electrode and being electrically connected to said tube; and

means for spacing said distal and proximal electrodes by a predetermined distance on the distal region of said wire.

21. A steerable guidewire as defined in claim 20 wherein said proximal spring is connected directly to said tube.

22. A steerable guidewire as defined in claim 21 wherein said proximal spring and said distal spring are coaxial with said wire.

23. A steerable guidewire as defined in claim 23 wherein the materials of said proximal electrode and said distal electrode are selected to approximately equalize the electrical resistances of the electrodes.

24. A steerable guidewire as defined in claim 23 wherein said proximal electrode is longer than said distal electrode, wherein said proximal electrode is fabricated of silver stainless steel and wherein said distal electrode is fabricated of platinum.

25. A steerable guidewire as defined in claim 20 wherein each electrode is fabricated of platinum.

26. A steerable guidewire as defined in claim 20 wherein said distal electrode is radiopaque.

27. A steerable guidewire as defined in claim 20 wherein said spacing means comprises a cylindrical insulating spacer having an outside diameter approximately equal to the outside diameters of said proximal and distal electrodes.

28. A steerable guidewire as defined in claim 20 wherein said tube, said proximal electrode and said distal electrode each have an outside diameter of about 0.020-inch or less.

29. A steerable guidewire as defined in claim 20 further including an insulating layer around said tube and said proximal electrode except for a portion of said proximal electrode adjacent to said spacing means.

30. A steerable guidewire as defined in claim 31 wherein said insulating layer comprises a polyimide tube.

31. A steerable guidewire as defined in claim 29 wherein said insulating layer comprises an insulating tube.

32. A steerable guidewire as defined in claim 20 wherein said tube is insulated from said wire by an insulating coating on said wire.

33. A steerable guidewire as defined in claim 20 wherein said tube is insulated from said wire by a polyimide sleeve on said wire.

34. A steerable guidewire as defined in claim 20 wherein said tube, said proximal electrode and said distal electrode have approximately the same outside diameters.

35. A steerable guidewire as defined in claim 20 further including a proximal conductive tube proximally spaced from said main tube and coaxial with said wire, said proximal tube being electrically connected to said wire.

36. A steerable guidewire as defined in claim 20 wherein said tube has an outside diameter of about 0.016-inch, and said wire has an outside diameter of about 0.008 inch.

37. A steerable guidewire as defined in claim 20 wherein said proximal electrode is spaced from the distal end of said tube and is electrically connected thereto by a conductive ribbon.

38. A steerable guidewire as defined in claim 37 wherein a region between the distal end of said tube and said proximal electrode is covered with a insulating tube.

39. A steerable guidewire as defined in claim 37 wherein said main conductive tube, said distal and proximal springs and said means for spacing each have an outside diameter not greater than about 0.020-inch.

40. A steerable guidewire as defined in claim 20 wherein said proximal electrode is spaced from the distal end of said tube, wherein a region between the distal end of said tube and said proximal electrode is covered with an insulating tube and wherein said proximal electrode is electrically connected to said tube.

* * * * *

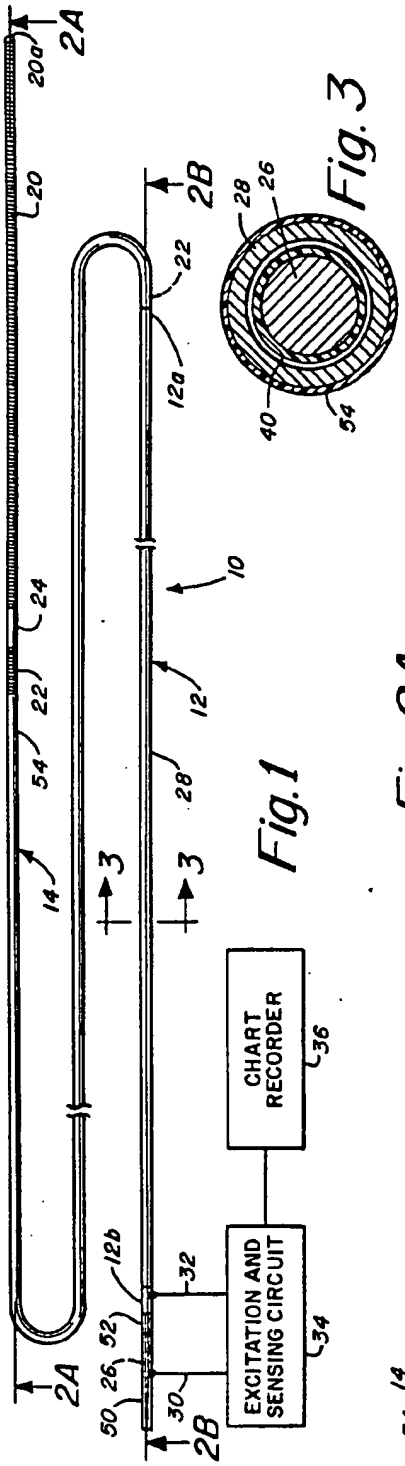


Fig. 1

Fig. 3

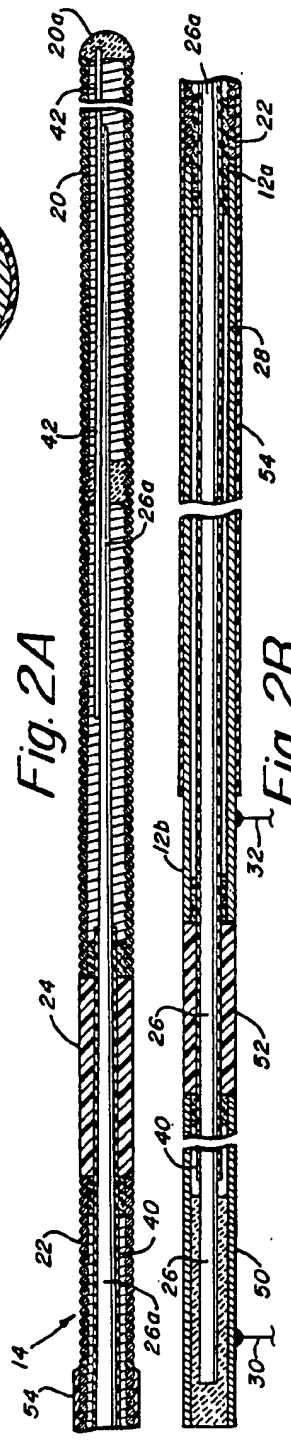


Fig. 2A

Fig. 2B

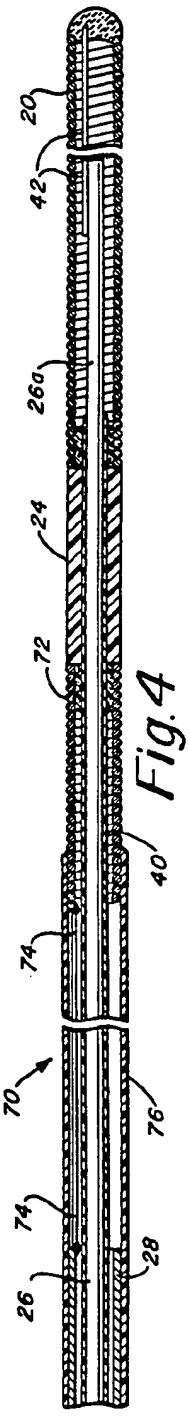


Fig. 4

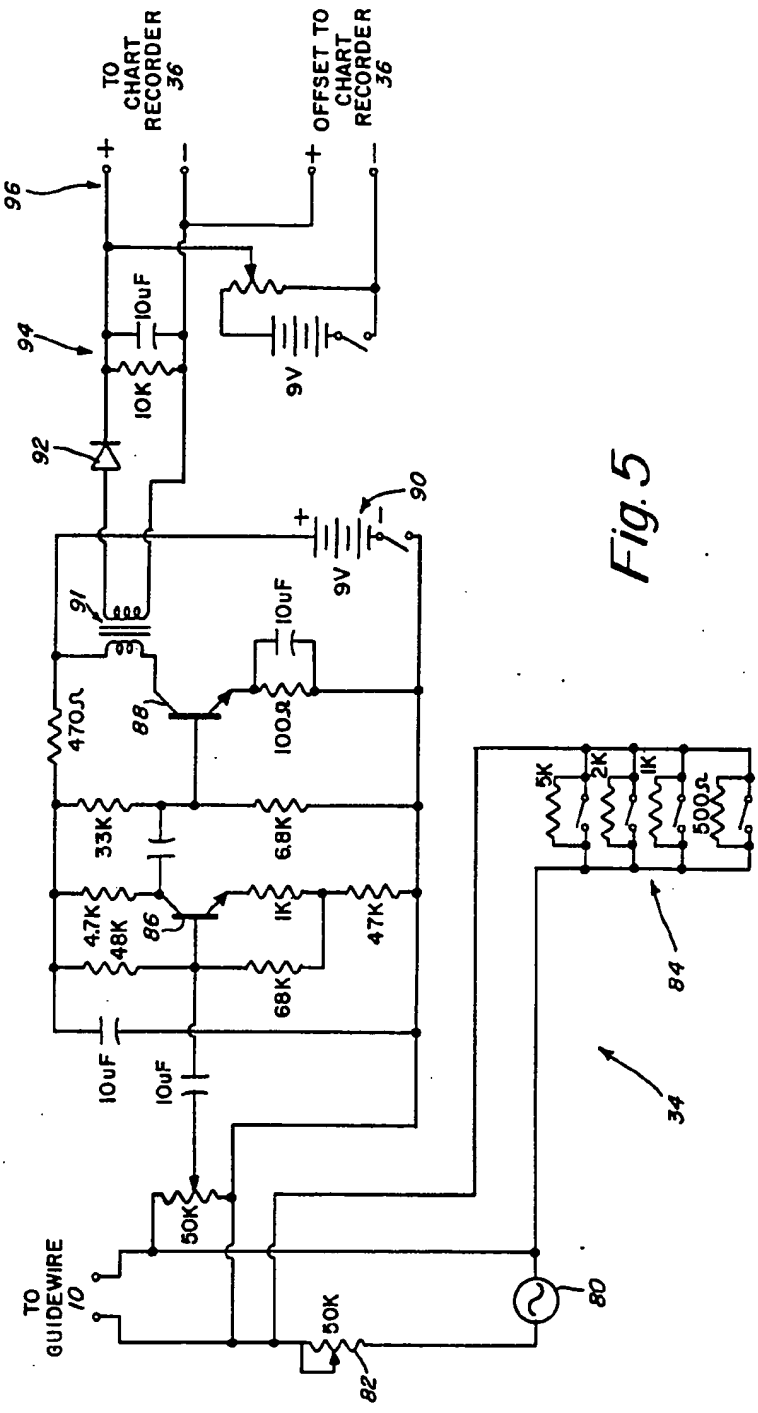

TO CHART RECORDER 36
OFFSET TO CHART RECORDER 36
96
94
92
90
91
88
86
84
34
80
82
10uF
10K
9V
470Ω
100Ω
33K
6.8K
4.7K
48K
1K
47K
68K
50K
5K
2K
500Ω
TO GUIDEWIRE 10

Fig. 5

STEERABLE GUIDEWIRE HAVING ELECTRODES FOR MEASURING VESSEL CROSS-SECTION AND BLOOD FLOW

FIELD OF THE INVENTION

This invention relates to a steerable guidewire that is used to guide a catheter in transluminal coronary angioplasty and, more particularly, to a small diameter, steerable guidewire that is provided with a pair of electrodes for measuring vessel cross-section and coronary blood flow.

BACKGROUND OF THE INVENTION

Transluminal coronary angioplasty involves the nonsurgical widening of a passage through an artery that has been narrowed or stenosed by deposits of plaque or plaque-ridden tissue. In one widely used approach, an inflatable balloon mounted on a catheter enlarges the passage through the deposit. In other known approaches the deposit is vaporized with laser energy transmitted through a catheter, or a passage is enlarged by plowing through the deposit with a hot tip device mounted at the distal end of a catheter. Regardless of the technique used for widening the passage through the obstruction, it is desirable for the cardiologist to measure the vessel cross-section before and after the angioplasty procedure in order to evaluate its effectiveness.

A device for measuring the cross sectional area of a blood vessel is disclosed in U.S. Pat. No. 3,896,373 issued July 22, 1975 to Zelby. Two electrodes that are spaced apart by a predetermined distance are secured to the outer surface of a catheter tube, and conductors extend from the electrodes through the tube to the proximal end of the catheter. The catheter carrying the electrodes is advanced through the blood vessel to a measurement site, and an AC voltage is applied to the electrodes. The voltage drop across the electrodes is indicative of the cross-sectional area of the blood vessel between the electrodes, since the applied voltage produces a current through the blood in the vessel.

In order to use the Zelby device in conjunction with an angioplasty procedure, the device is first advanced to the site of the obstruction to perform a measurement of vessel cross-section. Then the measurement device is withdrawn, and the balloon catheter is advanced to the obstructed site in order to perform the dilatation. Then the balloon catheter is withdrawn, and the measurement device is again advanced to the site to perform a second measurement of vessel cross-section. Since both the measurement device and the dilatation catheter can be difficult to advance to the obstructed site, the entire procedure is time consuming and is traumatic to the patient.

A dimension-sensitive angioplasty catheter having an inflatable balloon and a plurality of vessel-measuring electrodes near its distal end is disclosed in U.S. Pat. No. 4,587,985 issued May 13, 1986 to Salo et al. Each of the electrodes is mounted on the surface of the catheter tube and is individually connected to the proximal end of the catheter. One pair of electrodes is selected for connection to the output of an oscillator, and a second pair of electrodes is selected for sensing a signal that results from conduction through the blood in the vessel. While the Salo et al catheter avoids the problem of separate devices for vessel measurement and dilatation, the complexity of the device makes it difficult to fabricate with a sufficiently small diameter and sufficient flexibility for use in transluminal coronary angioplasty. In addition to the stiffness added by multiple electrodes, a separate conductor for each electrode passes through the catheter shaft.

Because of the requirement for accessing blood vessels of very small diameter, it has become commonplace in transluminal coronary angioplasty to use guidewires for controlling the placement of catheters. Catheters of sufficiently small diameter to be used in a small blood vessel typically lack the torsional rigidity to be adequately controlled as they are advanced through the vascular system to the obstructed site. Guidewires have an extremely small diameter, flexibility and sufficient torsional rigidity to be advanced to very small diameter blood vessels. The catheter is then advanced over the guidewire to the obstructed site. A steerable guidewire suitable for use in a balloon dilatation procedure is disclosed in U.S. Pat. No. 4,545,390 issued Oct. 8, 1985 to Leary and assigned to the assignee of the present application. The guidewire includes a small diameter, flexible rod having a distal region which is tapered. The tapered distal portion of the rod is surrounded by a helically-wound spring. The tip region of the guidewire is very flexible and can be bent to a predetermined shape which assists in guiding the device to an obstructed site. The guidewire disclosed in the Leary patent has no measurement capability.

A catheter including an intra-aortic balloon and a stylet normally used for twisting and untwisting the balloon is disclosed in U.S. Pat. No. 4,552,127, issued Nov. 12, 1985 to Schiff. An EKG electrode is affixed to the distal end of the stylet, and the stylet provides an electrical path from the EKG electrode to the proximal end of the catheter. A percutaneous lead that can be used for endocardial functions including mapping, ablation and pacing is disclosed in U.S. Pat. No. 4,660,571, issued Apr. 28, 1987 to Hess et al. In the Hess et al patent, a shaft utilized for torque control has an electrode at its distal end. The shaft functions as an electrical conductor from the electrode to the proximal end of the lead. An endocardial lead having a pair of spaced-apart, helically-wound electrodes on the outer surface of a flexible tube is disclosed in U.S. Pat. No. 4,481,953, issued Nov. 13, 1984 to Gold et al. A catheter for measuring blood flow including a pair of spaced-apart, helically-wound electrodes on the outer surface of a catheter tube is disclosed in U.S. Pat. No. 3,377,037, issued Nov. 20, 1973 to Kolin.

It is a general object of the present invention to provide a device for measuring the cross-sectional area of a blood vessel while avoiding the aforementioned problems.

It is another object of the present invention to provide improved methods and apparatus for measuring the cross-sectional area of a blood vessel and for measuring blood flow rate.

It is a further object of the present invention to provide a steerable guidewire having electrodes for measuring the cross-sectional area of a blood vessel and for measuring blood flow rate.

It is a further object of the present invention to provide a small diameter, steerable guidewire having a pair of spaced-apart electrodes near its distal end.

It is yet another object of the present invention to provide a small diameter, steerable guidewire having a

highly flexible tip portion provided with a pair of spaced-apart electrodes.

SUMMARY OF THE INVENTION

According to the present invention, these and other objects and advantages are achieved in a steerable guidewire comprising an elongated shaft having a distal end and a proximal end, and a tip attached to the distal end of the shaft. The shaft is sufficiently torsionally rigid along its length for controllably transmitting to the distal end substantially all of the rotation applied to the proximal end. The shaft includes a first electrical conductor and a second electrical conductor electrically insulated from each other. The electrical conductors extend from the distal end to the proximal end of the shaft. The tip is adapted to be bent to a desired curve. The tip is sufficiently flexible to adapt to and follow the contours of a blood vessel. The tip includes a distal electrode electrically connected to the one of the conductors and a proximal electrode electrically connected to the other of the conductors. The electrodes are axially spaced apart on the tip by a predetermined distance.

In a preferred embodiment, the distal electrode and the proximal electrode each comprise a conductive, helically-wound spring. The first conductor comprises a conductive tube having a lumen therethrough, and the second conductor comprises a wire extending through the lumen in the tube. The wire and the tube are separated by an insulating layer. The tip includes a tapered distal region of the wire extending beyond the distal end of the tube. The tapered distal region passes through the proximal spring and at least a portion of the distal spring. The distal spring is electrically connected to the tapered distal region of the wire, and the proximal spring is electrically connected to the tube. The proximal spring and the distal spring are axially spaced apart by an insulating spacer.

Preferably, the shaft and the tip have a diameter that does not exceed about 0.020 inch. The proximal spring, the distal spring, the spacer and the tube have approximately equal outside diameters to provide a smooth outer surface for passage through the vascular system. In one preferred embodiment, the distal electrode is radiopaque to assist in fluoroscopic location of the measurement site.

Preferably, the steerable guidewire of the invention includes an insulating layer around the tube and around the proximal electrode, except for a portion of the proximal electrode adjacent to the spacer. In one preferred embodiment, the proximal spring is connected directly to the conductive tube. In this embodiment, the proximal spring is typically longer than the distal spring, and the springs are made of different materials to approximately equalize the resistances of the electrodes. In another embodiment, the proximal spring is spaced from the tube and is electrically connected thereto by a thin conductive ribbon. In this embodiment both springs are made from the same material.

According to another aspect of the present invention, there is provided a method for measuring blood flow rate in a blood vessel. The method comprises the steps of advancing an elongated, flexible member having a pair of spaced apart electrodes thereon through a blood vessel to a selected measurement site, sensing electrical current flow between the electrodes, injecting a biologically-safe liquid having a conductivity different from that of blood into the blood vessel upstream from the electrodes, sensing a change in current flow between the electrodes resulting from injection of the liquid, and determining blood flow rate from the change in current flow between the electrodes resulting from injection of the liquid. Preferably, the elongated, flexible member is a steerable guidewire having electrodes mounted near the distal end thereof as described above. The steerable guidewire is typically advanced so that the electrodes are positioned downstream of a stenosed region in the blood vessel, and the liquid is injected upstream of the stenosed region. The injected liquid is preferably a glucose solution.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention together with other and further objects, advantages and capabilities thereof, reference is made to the accompanying drawings which are incorporated herein by reference and in which:

FIG. 1 illustrates a steerable guidewire system in accordance with the present invention;

FIG. 2A is an enlarged cross-sectional view of the steerable guidewire taken along the line 2A—2A of FIG. 1;

FIG. 2B is an enlarged cross-sectional view of the steerable guidewire taken along the line 2B—2B of FIG. 1;

FIG. 3 is a cross-sectional view of the guidewire shaft taken along the line 3—3 of FIG. 1;

FIG. 4 is an enlarged cross-sectional view of the distal end of the steerable guidewire in accordance with another embodiment of the invention; and

FIG. 5 is a schematic diagram of an excitation and sensing circuit suitable for use with the steerable guidewire.

DETAILED DESCRIPTION OF THE INVENTION

A guidewire system including a steerable guidewire having electrodes for measuring vessel cross-section and coronary blood flow is shown in FIGS. 1-3. The guidewire has a very small diameter and is adapted to be controllably guided through the vascular system to the coronary region. The guidewire includes a pair of electrodes near its distal end that can be used for measuring the cross-sectional area of a blood vessel and for measuring coronary blood flow.

As shown in FIG. 1, a guidewire 10 includes an elongated shaft 12 having a distal end 12*a* and a proximal end 12*b*. The guidewire 10 also includes a distal tip region 14 coupled to the distal end 12*a* of shaft 12. The shaft 12, which may have a length on the order of 150 centimeters, is highly flexible but is torsionally rigid so that substantially all the rotation applied to the proximal end 12*b* is transmitted to the distal end 12*a*. The distal tip region 14, which may have a length on the order of 32 centimeters, can be bent to a predetermined, curved configuration when relaxed but is sufficiently flexible so as to adapt to and follow the contours of a blood vessel. Further details regarding the construction and use of steerable guidewires are provided in the aforementioned Pat. No. 4,545,390, which is hereby incorporated by reference.

The distal tip region 14 of guidewire 10 is provided with a distal electrode 20 and a proximal electrode 22 spaced apart by an insulating member 24. The distal electrode 20 and the proximal electrode 22 are electrically connected through shaft 12 by conductive wire 26 and conductive tube 28, respectively, to the proximal